Evaluating Core Stability: Reliability and validity of hand-held dynamometry in measuring core strength

Masterproef voorgelegd tot het behalen van de graad van Master of Science in de Revalidatiewetenschappen en Kinesitherapie

Huyghe Melanie
Sercu Hanne
Vervaeke Olivier

Promotor: Prof. Dr. P. Roosen
Copromotor: Drs. C. De Blaiser
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Foreword

This research was done in the academic year 2015-2016 by Melanie Huyghe, Hanne Sercu and Olivier Vervaeke as completion of the master ‘Physiotherapy and rehabilitation sciences: musculoskeletal disorders’ at Ghent University. In the previous year, a systematic review “Clinical screening tests for core stability examination. A systematic review of intra- and intertester reliable and valid studies, in the context of measuring validity and reliability of hand-held dynamometry for the evaluation of core strength” was written.

Since October 2014 we have researched this topic. We have experienced this period as very interesting and instructive. In the beginning, we had good knowledge about the topic core stability, but did not know how to measure the core stability, strength and endurance. Furthermore, our knowledge about statistical analysis was poor. By writing a review and conducting this research we have learned more about this topic and statistical analysis and now, we present this article as result.

First of all, we would like to show our appreciation for the involvement of our supervisor, C. De Blaiser, who gave us the indispensable guidance to complete the research and write this article.

We would also like to thank Prof. dr. P. Roosen to give us an interesting subject to explore and for his valuable lectures during the past 5 years.

Last but not least we would like to thank our friends and family, to support us during the whole process.
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List of abbreviations

BMI  Body mass index
BioniX_fl0  BioniX flexion 0° mean
BioniX_fl30  BioniX flexion 30° mean
BioniX_ext0  BioniX extension 0° mean
BioniX_ext30  BioniX extension 30° mean
CI  Confidence intervals
CS  Core stability
d1_fl0_t1_gem  day 1 flexion 0° tester 1 mean
d1_fl30_t1_gem  day 1 flexion 30° tester 1 mean
d1_ext0_t1_gem  day 1 extension 0° tester 1 mean
d1_ext30_t1_gem  day 1 extension 30° tester 1 mean
d2_fl0_t1_gem  day 2 flexion 0° tester 1 mean
d2_fl30_t1_gem  day 2 flexion 30° tester 1 mean
d2_ext0_t1_gem  day 2 extension 0° tester 1 mean
d2_ext30_t1_gem  day 2 extension 30° tester 1 mean
d2_fl0_t2_gem  day 2 flexion 0° tester 2 mean
d2_fl30_t2_gem  day 2 flexion 30° tester 2 mean
d2_ext0_t2_gem  day 2 extension 0° tester 2 mean
d2_ext30_t2_gem  day 2 extension 30° tester 2 mean
d2_fl0_str_gem  day 2 flexion 0° straps mean
d2_fl30_str_gem  day 2 flexion 30° straps mean
d2_ext0_str_gem  day 2 extension 0° straps mean
d2_ext30_str_gem  day 2 extension 30° straps mean
EO  External oblique abdominis
ES  Erector spinae
FAPT  Front abdominal power test
HHD  Hand-held dynamometry
ICC  Intra-class correlation coefficient
MVIC  Maximal Voluntary Isometric Contraction
N  Newton
Nm  Newton meter
PIE  Performance Index Evaluation
<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tbody>
<tr>
<td>RA</td>
<td>Rectus Abdominis</td>
</tr>
<tr>
<td>SAPT</td>
<td>Side abdominal power test</td>
</tr>
<tr>
<td>SD</td>
<td>Standard deviation</td>
</tr>
<tr>
<td>sEMG</td>
<td>Surface Electromyography</td>
</tr>
<tr>
<td>T1</td>
<td>Tester 1</td>
</tr>
<tr>
<td>T2</td>
<td>Tester 2</td>
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Abstract in English and keywords

Background and objectives: Hand-held dynamometers are commonly used to assess strength of the upper and lower extremities during rehabilitation or sports injury prevention. For lots of movements, hand-held dynamometry (HHD) has already been validated, but not for the core muscles. The purpose of this study was to investigate a) the intra-and intertester reliability of measurements of trunk flexion and extension in two different positions, b) the concurrent validity of the HHD measurements compared to an electromechanical dynamometer ‘BioniX’ as the gold standard and c) the comparability of results obtained in the different positions.

Methods: Twenty-nine adults (14 females and 15 males) participated in this study. Maximal isometric flexion and extension torques (for BioniX in Newton meter (Nm)) and forces (in Newton (N) for the HHD) were measured in two positions: lying with 0° trunk flexion and lying with 30° trunk flexion. Measurements on day one were performed with the hand-held dynamometer by tester 1 (T1) and were repeated using the BioniX. Measurements on day two were performed with the hand-held dynamometer by T1, tester 2 (T2) and by the straps. Intra- and intertester reliability were determined using the intra-class correlation coefficient (ICC). All HHD forces were converted to torques, to compare to the BioniX measurements. A paired student’s t-test and linear regression between HHD values and BioniX measurements were performed to determine validity of the HHD measurements. Student’s t-test was also used to compare data from different positions.

Results: Intratester reliability for flexion and extension in the two positions were excellent (ICC = 0.802 – 0.965). Excellent intertester reliability between T1 and T2 was also found in all positions. Comparing T1/T2 with the straps showed results varying from good to excellent. Only when comparing T1/T2 with the straps in the neutral position for extension, ICC values were poor to fair (0.389 – 0.541). Pearson correlation coefficients between BioniX and HHD values of day one by T1 ranged from 0.559 to 0.862. All correlation coefficients were demonstrated significant (p<0.001). Linear regression was rather good in all tests. A difference was seen between the test positions for HHD as well as for the BioniX. For HHD, the mean score of all tests in 0° was lower than the tests in 30° except for the flexion test with the straps. Not all differences were significant. For the BioniX, the mean score of all tests in 0° were lower than the tests in 30°. All differences were significant (p<0.001). The mean scores of all HHD tests were significant lower (p<0.001) than the BioniX values.

Conclusion: The results suggest that HHD used in a 30° flexion position offers a feasible, inexpensive and portable test of trunk flexors and extensors in a healthy population. It underestimates the
absolute strength both for flexion and extension compared to the BioniX, but it is a useful tool to assess quick and objective the physical function in the clinical setting.

**Keywords:** trunk flexion, trunk extension, strength testing, BioniX, isometric testing
Abstract in Dutch

Achtergrond en doelstellingen: Hand-held dynamometrie (HHD) is een veelgebruikte methode voor het meten van kracht in onderste en bovenste ledematen bij het evalueren van revalidatievorderingen of bij letselpreventie. HHD is dan ook al voor veel verschillende bewegingen gevalideerd. Deze methode werd echter nog niet toegepast bij rompflexie en -extensie. Het doel van deze studie was dan ook om a) de inter- en intratester betrouwbaarheid te onderzoeken bij rompflexie en -extensie vanuit twee verschillende posities, b) deze twee posities onderling te vergelijken en c) de validiteit na te gaan door deze methode te vergelijken met een elektromechanische dynamometer ‘BioniX’, een gouden standaard voor rompflexie en -extensie.

Methode: Negenentwintig volwassenen (14 vrouwen en 15 mannen) namen deel aan deze studie. Maximale flexie- en extensiekracht werd gemeten in twee posities: liggen met 0° rompflexie en liggen met 30° rompflexie. Op dag één testte tester 1 (T1) door middel van HHD, gevolgd door dezelfde testen in de BioniX. Op dag twee werden dezelfde metingen met HHD herhaald door T1, tester 2 (T2) en door middel van een fixatiegordel. Intra- en intertester betrouwbaarheid werden geëvalueerd door middel van de intra-class correlation coefficient (ICC). Alle HHD krachtwaarden werden omgezet naar draaimomenten, om zo met de BioniX waarden te vergelijken. Om de validiteit te bepalen werd een gepaarde student’s t-test en lineaire regressie tussen HHD en BioniX gedaan. Daarnaast werd ook een gepaarde student’s t-test gebruikt om de resultaten in de verschillende posities te vergelijken.

Resultaten: Intratester betrouwbaarheid was excellent voor flexie en extensie in beide posities (ICC = 0.802 – 0.965). Intertester betrouwbaarheid tussen T1 en T2 was in elke positie excellent. Intertester betrouwbaarheid tussen T1/T2 met de fixatiegordel varieerde van goed tot excellent behalve bij de extensietest vanuit neutrale positie, hierbij werden ICC waarden zwak tot billijk bevonden (ICC = 0.389 – 0.541). Pearson correlatie coëfficiënten tussen BioniX en HHD waarden van T1 op dag 1 lagen tussen 0.559 en 0.862 en waren telkens significant (p<0.001). Lineaire regressie was goed in alle testen. Bij HHD waren alle gemiddelde scores van de testen vanuit 0° lager dan deze van de testen in 30° behalve voor de flexie test met fixatiegordels. Deze verschillen waren niet altijd significant. Bij de BioniX waren de gemiddelde waarden van de testen in 0° telkens significant lager dan deze in 30° (p<0.001). De gemiddelde waarden van alle HHD testen waren significant lager dan deze van de BioniX.
Conclusies: Deze resultaten suggereren dat HHD vanuit de 30° flexie positie een waardig, betaalbaar en draagbaar alternatief vormt voor het testen van rompflexie en -extensie in een gezonde populatie. Deze methode onderschat de absolute kracht die behaald wordt in de BioniX, maar is een nuttige methode voor het snel en objectief meten van kracht in een klinische setting.

Keywoorden: Rompflexie, rompextensie, kracht test, isometrische test, BioniX
1. Introduction

The importance of the central core for body stabilisation and force generation in all sports activities is being increasingly recognised (1). Kibler et al. (1) defined core stability (CS) as the ability to control the position and motion of the trunk over the pelvis and legs to allow optimum production, transfer and control of force and motion to the terminal segment in integrated kinetic chain activities. The muscles and joints of the hip, pelvis and spine are centrally located to be able to perform many of the stabilising functions that the body will require to provide proximal stability for distal mobility and functioning of the limbs (1). In addition to its local functions of stability and force generation, core activity is involved with almost all extremity activities such as running, kicking and throwing (1). The main function of CS is described as withstanding compression forces on the spine and returning the body to equilibrium after perturbation (2).

In athletes it has been shown that a poor CS is a risk factor for back and lower extremity injury, which proves the importance for athletes to add CS exercises to their training program (3). The position, motion and contributions of the core must be evaluated and treated as part of the evaluation and treatment of sports related musculoskeletal injuries (4).

Important components of CS are endurance, strength, power and sensory-motor control of the abdominal, hip and spine musculature (2). Although the terms CS and core strength are sometimes used interchangeably, the authors have chosen to subsume core strength within CS. Despite the different techniques, such as isometric dynamometry and functional tests to measure CS, there still does not exist a gold standard (1). It is difficult to test CS with a single test, because of the complex interplay between different aspects that contribute to CS (3). Often, evaluation of specific motion patterns and quality of movement are performed in the evaluation of CS (1). This method of analysis is hard to quantify but is similar to the actual three-planar core function.

Renewed interest in movement screening has developed a need for valid, reliable and objective clinical tests (5). Furthermore, results of CS testing can be used to assess injury or re-injury risk and to observe preoperative and postoperative rehabilitation status (3). To date, there is a lack of tests that are proved reliable and/or valid. Therefore, the purpose of the systematic review presented last year was to systematically summarise different tests that assess CS and determine which of them are valid and reliable.
The included studies were divided in three categories: four articles investigated a test to evaluate general CS (6, 7, 8, 9), four to evaluate core endurance (12, 13, 14, 15) and five to evaluate core strength (2, 3, 10, 11, 18).

Four out of 13 articles, examined the inter- and/or intratester reliability (9, 10, 13, 14). Five of the articles investigated the test-retest reliability (3, 10, 12, 13, 15). By analyzing the results of this review, the authors could conclude that some tests for measuring CS are proved reliable. Reliability was tested in different ways in 8 articles: intra- and intertester and test-retest reliability. Intratester reliability was investigated in bridge with unilateral knee extension (13) and in a battery of 6 clinical tests including frontal plane evaluation, sagittal plane evaluation, transverse plane evaluation, unilateral squat, lateral step-down and bridge (9), and was respectively fair to moderate and low. Intertester reliability ranged between low and high. Comparable with intratester reliability, the battery of 6 clinical tests had a low intertester reliability (9). The bridge with unilateral knee extension (13), Performance Index Evaluation (PIE) (10) and modified testing procedure for trunk flexion and extension (14) had respectively substantial, high among men’s college players and high intertester reliability. 5 articles investigated test-retest reliability. The bridge with unilateral knee extension (13), front abdominal power test (FAPT) and side abdominal power test (SAPT) (3) and sport-specific endurance plank test (15) had an excellent test-retest reliability. Power (chop and lift) and endurance (Biering-Sørensen and side-plank left and right) tests (17) had respectively high and moderate to high test-retest reliability. PIE (15) had an unacceptable test-retest reliability. The 6 single-leg stance tests from Weir et al. (2010) had a low inter- and intratester reliability (9). Only one of them, bridge with unilateral knee extension (13), is moderate to excellent for intertester, intratester and test-retest reliability. Therefore, the utilization of this test in a clinical setting may be recommended. If tests with low reliability are used in practice, results should be interpreted cautiously.

Validity has only been measured in three studies, but only two of them were able to validate the test (14, 15), which indicates that further research is important to evaluate CS tests in methodological studies. Reiman et al. (14) investigated the standard trunk endurance testing for flexion and extension by two different tests (first time with hips and knees 90° bended, second time with the lower extremities held down). The second extension ICC was 0.97, the first flexion ICC was 0.93. Correlation analysis between the two procedures had a pearson r=0.84 for flexion and r= 0.90 for the extension positions. Tong et al. (2013) (15) performed the sport-specific endurance plank test passing 9 stages without rest and validated the Surface Electromyography (sEMG) of the Rectus Abdominis,
external oblique abdominis (EO) and Erector Spinae (ES) as a percentage of the correlating Muscle Voluntary Isometric Contraction (MVIC) during the test. There was a significant increase of muscle activation in all tested muscles. Plank test performance was reduced significantly with pre-fatigue core work out. At present, only one test is proved both reliable and valid to evaluate CS (15). Because there was a lack of a gold standard to measure core endurance and general CS, almost no tests are validated. An electromechanical dynamometer can be seen as a gold standard to measure strength (21). Recently the BioniX is developed which is an electromechanical dynamometer to measure core strength (35).

Points of discussion in our systematic review based on literature data were the ambiguous communication about CS: different names to describe the same test were used. Biering-Sørensen was also described as trunk extension test (15) or modified trunk extension endurance test (14). There was also no uniform interpretation of the ICC. Only two articles (13, 14) appointed the cut-off values for the level of reliability and validity. Two different cut-off values were used in these articles, so it was difficult to interpret the reliability and validity of these tests.

There are two options for objectively measuring muscle strength: isokinetic testing and HHD (21). Isokinetic dynamometers such as the BioniX or Biodex are computerized machines capable of providing multiple elements of measuring static and dynamic muscle strength, including peak force, power and angle of maximal force. Isokinetic muscle testing is considered a reliable and valid instrument for muscle force testing (22, 23, 24, 25, 26) and is often used as a gold standard to compare other instruments of measurement that test muscle strength (21). However, the use of isokinetic dynamometers in large-scale epidemiological studies is limited, because the equipment is expensive and not portable (16). Furthermore, the existing tests are often time-consuming. There is a need for a valid and reliable tool to objectify CS in a clinical setting. This tool should be inexpensive and easy to use. HHD was first described by Lovett and Martin in 1916 (27). It is a convenient device that can be placed between the hand of the practitioner and the patient’s tested body part, similar to how a practitioner would perform a manual muscle test. Unlike manual muscle testing, it provides a quantified measurement of force. If HHD demonstrates accuracy when compared with isokinetic measurement, its ease of use, cost and convenient size may justify further widespread clinical use.

The purposes of this study were to examine validity and reliability of static trunk flexion and extension strength tests by HHD in a healthy population. Furthermore, also the comparability of
results obtained in the different test positions in the HHD tests and in the BioniX tests were analyzed. Validity was evaluated by comparing HHD with the tests using BioniX, which can be seen as the gold standard (21). Inter- and intratester reliability were evaluated by comparing results of HHD tests measured by T1, T2 and straps and tests measured by T1 on two different days respectively.
2. Methods

This study was approved by Bimetra and the Ethics committee of the University of Ghent and was conducted at the University of Ghent in April 2015. Data was collected during April 2015 and processed in June 2015.

2.1 Selection of participants

Twenty-nine healthy participants, 15 men (mean age of 21,87 ±1,06 years, mean height of 1,80±0,07 m, mean weight of 72,25 ±5,86 kg and mean BMI of 22,31 ±1,62 kg/m²) and 14 women (mean age of 21,64 ±1,45 years, mean height of 1,70±0,04 m, mean weight of 63,31 ±5,18 kg and mean BMI of 22,01 ±1,55 kg/m²), were recruited in April 2015 by the testers MH, HS and OV, who contacted acquaintance and students of the University of Ghent. Table 1 represents the anthropometric data of the participants. Full ethical approval was obtained for the study and written informed consent was obtained from all participants (appendix 6). The participants were allowed to withdraw from the study at any stage of the trial. Following inclusion criteria were used: age between 18 and 35 years, absence of a treatment for back pain in his/her whole life, a body mass index lower than 30 and length lower than two meters. Participants who experienced a presence of cramps or pain before or during the test were excluded from the dataset.

Table 1: anthropometric data of the participants

<table>
<thead>
<tr>
<th></th>
<th>Mean</th>
<th>SD (Standard deviation) (±)</th>
<th>Range</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>Male</td>
<td>Female</td>
<td>Male</td>
</tr>
<tr>
<td>Age (years)</td>
<td>21,87</td>
<td>21,64</td>
<td>1,06</td>
</tr>
<tr>
<td>Length (m)</td>
<td>1,80</td>
<td>1,70</td>
<td>0,07</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>72,25</td>
<td>63,31</td>
<td>5,86</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>22,31</td>
<td>22,01</td>
<td>1,62</td>
</tr>
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</table>

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2.2 Test procedure

Two testing days to test the reliability and validity of the isometric tests for trunk flexion and extension using HHD were organized in April 2015. An overview of this test procedure is given in a table (Appendix 1). The two testing sessions were separated by 7 days. The first day, participants got informed about the purpose of the study and how the test days would proceed. Length, weight and current age were recorded before commencement of testing. The test procedure was performed in the same order for all the participants. At first, every subject performed the isometric trunk flexion and extension protocol with a hand-held dynamometer tested by T1. Afterwards, fifteen minutes were given as a moment of rest, before the BioniX protocol was completed. On the second testing day, the isometric protocol with HHD was performed three times, measured in different ways. Before the tests, a short questionnaire was completed to evaluate the load of the activities of the participants in the last days before the testing day and muscle soreness to make sure this would not interfere with the test results (Appendix 2). In order to compare HHD results in N with BioniX results in torque (Nm), T1 measured the distance between the nipple line and the ASIS and the distance between the anguli inferii and the PSIS. After this measurement, the isometric trunk tests were tested by T1 using a hand-held dynamometer. After a fifteen minute break, the tests were repeated by T2. In the end, after another fifteen minute break, the isometric trunk flexion and extension protocol was repeated using a belt to fixate the hand-held dynamometer on the thorax of the subject.

The subjects wore sport shorts and were barefoot. To reduce the interference of clothes during the testing sessions, male subjects completed the test without a T-shirt and female subjects wore a sports bra or a slim fit T-shirt. To perform the isometric protocol using HHD, the testers (T1 and T2) completed multiple training sessions before the test procedure was started.

2.3 Measurement procedure

2.3.1 HHD

Two test variations for trunk flexion and two variations for trunk extension were measured by HHD. Therefore, one peak force per test was measured using a Biometrics microFet 2 hand-held dynamometer. Subjects were tested on a treatment table, which had the same height during all the isometric HHD tests. The tester stood next to the participant and resisted the movement with his both arms perpendicular to the subject. Before testing each variation, one submaximal try-out took place. Afterwards, the subjects performed each variation for three times during five seconds. Between each trial, the subjects got ten seconds of rest. During all these tests, the testers gave a
standardised command and encouragement. The positioning of the hand-held dynamometer was standardised in each subject. The outcome measure of the isometric tests was N.

*Isometric trunk flexion 0° (Appendix 3A)*

Subjects laid supine in neutral position, fixed by two belts, one ten cm above the knee and the second one over the ASIS. The arms of the subjects were resting on their abdomen. The HHD was placed on the sternum between the nipples.

*Isometric trunk flexion 30° (Appendix 3B)*

The head of the table was 30° inclined, this was measured with a goniometer by T1 and T2. The subject laid supine with his back fully on the head of the table. They were fixed by two belts, on the same position as during the isometric trunk flexion 0°. The arms of the subjects were resting on their abdomen. The HHD was placed on the sternum between the nipples.

*Isometric trunk extension 0° (Appendix 3C)*

Subjects laid prone in neutral position, fixed by two belts, one ten cm above the knee and the second one just under the tuber ischiadici. The arms of the subjects were resting on the treatment table, next to the subjects’ body. The HHD was placed on the back, between the angeli inferii.

*Isometric trunk extension 30° (Appendix 3D)*

The head of the table was 30° declined, measured with a goniometer by T1 and T2. The subjects laid prone on the treatment table, with the ASIS on the axis. They were fixed by two belts, one ten cm above the knee and the second one just beneath the tuber ischiadici. The arms of the subjects were resting on the treatment table, next to the subjects’ body. The HHD was placed on the back, between the angeli inferii.

**2.3.2 BioniX**

The electromechanical dynamometer BioniX Sim3 Pro was used. At the start of the tests in the BioniX, subjects got informed about the operation of the machine. As shown in figure A, the participants were asked to stand barefoot on the BioniX as a safety measurement (appendix 4A). The BioniX was adapted to the anatomical characteristics of each subject. The subjects grabbed the handlebars with crossed arms and were fixed at the level of the shoulders and ASIS. Analogous to HHD, two isometric test variations for trunk flexion and two isometric variations for trunk extension
were completed in the BioniX. Before each variation of the tests, one submaximal try-out took place. Afterwards, every test was performed for three times during five seconds with ten seconds of rest in between. During all the tests, the testers gave the same commands and encouragement analogous to the isometric trunk flexion and extension test with hand-held dynamometer. The outcome measure of the BioniX tests was torque (Nm).

Isometric trunk flexion 0° (Appendix 4A)
Subjects were standing in a neutral position. An isometric trunk flexion was performed against resistance of the BioniX at the level of the shoulders.

Isometric trunk flexion 30° (Appendix 4B)
Subjects were standing in 30° of trunk flexion and performed an isometric trunk flexion against resistance of the BioniX at the level of the shoulders.

Isometric trunk extension 0° (Appendix 4A)
Subjects were standing in a neutral position. An isometric trunk extension was performed against resistance of the BioniX at the level of the shoulders.

Isometric trunk extension 30° (Appendix 4B)
Subjects were standing in 30° of trunk flexion and performed an isometric trunk extension against the resistance of the BioniX at the level of the shoulders.

2.4 Statistical analysis
Statistical analysis was conducted with commercial software (IBM SPSS Statistics 23.0). All data of every HHD and BioniX test were examined for normal distribution using the Shapiro-Wilk test and was confirmed allowing use of parametric tests for analysis.

2.4.1 Reliability
Both intra- and intertester reliability was examined, respectively using measurements of T1 on the first day and T1 on the second day and measurements of T1, T2 and straps on the second day. To determine inter- and intratester reliability, the ICC coefficients were calculated using a 2,k and 3,k model with absolute agreement and 95% confidence intervals (CI). The strength of ICC’s was interpreted as follows: values <0.40 represented poor reliability, values between 0.40 and 0.59
indicated fair reliability, values between 0.60 and 0.74 indicated good reliability and values > 0.75 marked excellent reliability (19).

2.4.2 Validity
To determine if HHD is a valid tool to measure core strength, validity was assessed comparing HHD values with the BioniX measurements. HHD values were converted from N to Nm by multiplying the mean force with the measured distance between the nipple line and the ASIS for flexion or the distance between the anguli inferii and the PSIS for extension.
To measure validity of HHD against the BioniX data as ground truth, three different metrics were used. At first, pearson correlation coefficient between HHD of T1 on the first day and BioniX was analyzed. Secondly, linear regression analysis was performed to assess which HHD test best predicted the BioniX. At last, paired t-tests were run to determine if there were any significant differences between the BioniX and HHD.

2.4.3 Differences in test positions
A paired students t-test was used to evaluate significant differences between the two testing positions: 0° and 30° flexion or extension both for the HHD values as for the BioniX values.
3. Results

3.1 Reliability

3.1.1 Intratester reliability
Intratester reliability was tested only in T1 and was excellent in flexion 0° (ICC\(_{2,k}\) = 0.802, 95% CI: 0.574 – 0.908, p < 0.001), excellent in flexion 30° (ICC\(_{2,k}\) = 0.946, 95% CI: 0.886 – 0.975, p < 0.001), excellent in extension 0° (ICC\(_{2,k}\) = 0.808, 95% CI: 0.224 – 0.932, p < 0.001) and excellent in extension 30° (ICC\(_{2,k}\) = 0.965, 95% CI: 0.926 – 0.984, p < 0.001).

3.1.2 Intertester reliability
Intertester reliability between T1 and T2 was excellent in all tests: flexion 0° (ICC\(_{2,k}\) = 0.884, 95% CI: 0.530 – 0.958, p < 0.001), flexion 30° (ICC\(_{2,k}\) = 0.958, 95% CI: 0.892 – 0.982, p < 0.001), extension 0° (ICC\(_{2,k}\) = 0.777, 95% CI: 0.428 – 0.904, p < 0.001) and extension 30° (ICC\(_{2,k}\) = 0.898, 95% CI: 0.261 – 0.970, p < 0.001).

Intertester reliability between T1 and straps was excellent for flexion 0° (ICC\(_{3,k}\) = 0.813, 95% CI: 0.598 – 0.912, p < 0.001) and flexion 30° (ICC\(_{3,k}\) = 0.761, 95% CI: 0.103 – 0.914, p < 0.001), poor for extension 0° (ICC\(_{3,k}\) = 0.389, 95% CI: -0.175 – 0.752, p < 0.001) and excellent for extension 30° (ICC\(_{3,k}\) = 0.795, 95% CI: 0.166 – 0.928, p < 0.001).

Intertester reliability between T2 and straps was good for flexion 0° (ICC\(_{3,k}\) = 0.672, 95% CI: 0.313 – 0.845, p < 0.001), for flexion 30°, it was excellent (ICC\(_{3,k}\) = 0.805, 95% CI: 0.384 – 0.923, p < 0.001), extension 0° was fair (ICC\(_{3,k}\) = 0.541, 95% CI: -0.230 – 0.825, p < 0.001) and extension 30° was excellent (ICC\(_{3,k}\) = 0.825, 95% CI: 0.629 – 0.918, p < 0.001).

3.2 Validity

3.2.1 Correlation coefficients of HHD and BioniX
The Pearson correlation coefficients between BioniX values and HHD of day one by T1 are shown in table 2. The correlation coefficients for the tests in flexion ranged from 0.723 to 0.862. Extension tests revealed lower correlation coefficients, ranging from 0.559 to 0.748. For all tests, correlation coefficients were demonstrated significant (p<0.001). The correlation coefficients were highest amongst the same test positions in flexion: 0.823 for flexion 0° and 0.862 in flexion 30°. In opposition
to flexion, the trunk extension tests demonstrated the highest correlation with extension 30° in the HHD test, both for 0° and 30° BioniX tests.

Table 2: Correlation coefficients of HHD and BioniX

<table>
<thead>
<tr>
<th></th>
<th>BioniX flexion 0°</th>
<th>BioniX flexion 30°</th>
<th>BioniX extension 0°</th>
<th>BioniX extension 30°</th>
</tr>
</thead>
<tbody>
<tr>
<td>HHD day 1 T1</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>flexion 0°</td>
<td>0.823**</td>
<td>0.723**</td>
<td></td>
<td></td>
</tr>
<tr>
<td>flexion 30°</td>
<td>0.822**</td>
<td>0.862**</td>
<td></td>
<td></td>
</tr>
<tr>
<td>extension 0°</td>
<td>0.633**</td>
<td></td>
<td>0.559**</td>
<td></td>
</tr>
<tr>
<td>extension 30°</td>
<td>0.748**</td>
<td>0.733**</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

* p< 0.005; ** p<0.001

3.2.2 Linear regression analysis of HHD and BioniX

Simple linear regression analyses were done with BioniX values as dependent variables and HHD T1 values as independent variables. The visual relationship between the HHD tests and BioniX tests is given in the graphs below. BioniX values could be predicted significantly by all HHD values (p < 0.001). Generally, the regression equation can be interpreted as follows: BioniX value = a + b x HHD value. All regression equation and corresponding R² values can be seen in the graphs. The linear regression was good for the flexion tests. On the other hand, in extension the linear regression showed only a good fit for the HHD extension 30° test. The same results could be seen in the Pearson correlation coefficients.
Figure 1: Linear regression HHD flexion 0° and BioniX flexion 0°

\[ y = 25.33 + 2.04x \]

\( R^2 = 0.678 \)

day 1 flexion 0° tester 1 mean

Figure 2: Linear regression HHD flexion 30° and BioniX flexion 30°

\[ y = 17.56 + 1.37x \]

\( R^2 = 0.773 \)

day 1 flexion 30° tester 1 mean
Figure 3: Linear regression HHD flexion 30° and BioniX flexion 0°

\[ y = 0.93x + 1.34 \]

\[ R^2 = 0.676 \]

day 1 flexion 30° tester 1 mean

Figure 4: Linear regression HHD flexion 0° and BioniX flexion 30°

\[ y = 0.20x + 1.75 \]

\[ R^2 = 0.523 \]

day 1 flexion 0° tester 1 mean
Figure 5: Linear regression HHD extension 0° and BioniX extension 0°

\[
\text{BioniX extension 0°} = 3.85 + 1.16 \times \text{day 1 extension 0° tester 1 mean}
\]

\[R^2 = 0.440\]

Figure 6: Linear regression HHD extension 30° and BioniX extension 30°

\[
\text{BioniX extension 30°} = 54.3 + 1.77 \times \text{day 1 extension 30° tester 1 mean}
\]

\[R^2 = 0.538\]
Figure 7: Linear regression HHD extension 30° and BioniX extension 0°

\[ R^2 = 0.559 \]

Figure 8: Linear regression HHD extension 0° and BioniX extension 30°

\[ R^2 = 0.395 \]
3.2.3 Comparison of the means of HHD and BioniX

As seen in table 3, the mean score of all HHD tests was significant lower (p<0.001) than the BioniX values. The range is lowest between the BioniX in 0° and HHD tests, because the mean BioniX values in 30° were always higher than the neutral position. Furthermore, the BioniX tests had higher SD’s for every test in comparison to the HDD tests.

<table>
<thead>
<tr>
<th></th>
<th>Mean (Nm)</th>
<th>SD (±)</th>
<th>t</th>
<th>Sig</th>
</tr>
</thead>
<tbody>
<tr>
<td>d1_fl0_t1_gem</td>
<td>72,864</td>
<td>18,9231</td>
<td>-8,21</td>
<td>&lt;0,001</td>
</tr>
<tr>
<td>BioniX_fl0</td>
<td>123,472</td>
<td>46,9716</td>
<td></td>
<td></td>
</tr>
<tr>
<td>d1_fl0_t1_gem</td>
<td>72,865</td>
<td>18,9231</td>
<td>-9,927</td>
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</tr>
<tr>
<td>BioniX_fl30</td>
<td>136,788</td>
<td>45,8004</td>
<td></td>
<td></td>
</tr>
<tr>
<td>d1_fl30_t1_gem</td>
<td>87,283</td>
<td>28,9129</td>
<td>-6,848</td>
<td>&lt;0,001</td>
</tr>
<tr>
<td>BioniX_fl0</td>
<td>123,472</td>
<td>46,9716</td>
<td></td>
<td></td>
</tr>
<tr>
<td>d1_fl30_t1_gem</td>
<td>87,283</td>
<td>28,9129</td>
<td>-10,458</td>
<td>&lt;0,001</td>
</tr>
<tr>
<td>BioniX_fl30</td>
<td>136,788</td>
<td>45,8004</td>
<td></td>
<td></td>
</tr>
<tr>
<td>d1_ext0_t1_gem</td>
<td>135,677</td>
<td>31,2094</td>
<td>-7,235</td>
<td>&lt;0,001</td>
</tr>
<tr>
<td>BioniX_ext0</td>
<td>195,371</td>
<td>57,0136</td>
<td></td>
<td></td>
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<tr>
<td>d1_ext0_t1_gem</td>
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<td>31,2094</td>
<td>-7,11</td>
<td>&lt;0,001</td>
</tr>
<tr>
<td>BioniX_ext30</td>
<td>218,409</td>
<td>76,1539</td>
<td></td>
<td></td>
</tr>
<tr>
<td>d1_ext30_t1_gem</td>
<td>155,681</td>
<td>33,3814</td>
<td>-5,713</td>
<td>&lt;0,001</td>
</tr>
<tr>
<td>BioniX_ext0</td>
<td>195,371</td>
<td>57,0136</td>
<td></td>
<td></td>
</tr>
<tr>
<td>d1_ext30_t1_gem</td>
<td>155,681</td>
<td>33,3814</td>
<td>-6,294</td>
<td>&lt;0,001</td>
</tr>
<tr>
<td>BioniX_ext30</td>
<td>218,409</td>
<td>76,1539</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

3.3 differences in test positions

3.3.1 BioniX

The mean score for the flexion tests as well as for the extension tests of both in 0° was also lower than the mean scores for the tests in 30°. Both differences were significant (table 4).

<table>
<thead>
<tr>
<th></th>
<th>Mean (Nm)</th>
<th>SD (±)</th>
<th>t</th>
<th>Sig</th>
</tr>
</thead>
<tbody>
<tr>
<td>BioniX_fl0</td>
<td>123,472</td>
<td>46,9716</td>
<td>-3,643</td>
<td>&lt;0,001</td>
</tr>
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<td>BioniX_fl30</td>
<td>136,788</td>
<td>45,8004</td>
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<td></td>
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<tr>
<td>BioniX_ext0</td>
<td>195,371</td>
<td>57,0136</td>
<td>-4,565</td>
<td>&lt;0,001</td>
</tr>
<tr>
<td>BioniX_ext30</td>
<td>218,409</td>
<td>76,1539</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
3.3.2 HHD

Except for the flexion tests with the straps, the mean score of all tests in 0° was significant lower than the tests in 30° (Table 5).

Table 5: Student’s t test HHD

<table>
<thead>
<tr>
<th></th>
<th>Mean (Nm)</th>
<th>SD (±)</th>
<th>t</th>
<th>Sig</th>
</tr>
</thead>
<tbody>
<tr>
<td>d1_fl0_t1_gem</td>
<td>72,864</td>
<td>18,9231</td>
<td>-4,054</td>
<td>&lt;0,001</td>
</tr>
<tr>
<td>d1_fl30_t1_gem</td>
<td>87,283</td>
<td>28,9129</td>
<td></td>
<td></td>
</tr>
<tr>
<td>d1_ext0_t1_gem</td>
<td>135,677</td>
<td>31,2094</td>
<td>-5,086</td>
<td>&lt;0,001</td>
</tr>
<tr>
<td>d1_ext30_t1_gem</td>
<td>154,394</td>
<td>31,5401</td>
<td></td>
<td></td>
</tr>
<tr>
<td>d2_fl0_str_gem</td>
<td>67,37</td>
<td>23,1625</td>
<td>-0,524</td>
<td>0,605</td>
</tr>
<tr>
<td>d2_fl30_str_gem</td>
<td>65,909</td>
<td>23,3467</td>
<td></td>
<td></td>
</tr>
<tr>
<td>d2_ext0_str_gem</td>
<td>102,93</td>
<td>28,9067</td>
<td>-9,696</td>
<td>&lt;0,001</td>
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<tr>
<td>d2_ext30_str_gem</td>
<td>135,303</td>
<td>31,7936</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
4. Discussion

4.1 Reliability
This study has shown that the intratester reliability of measuring trunk strength in flexion and extension by HHD is excellent for all test positions, especially for the flexion 30° and extension 30°. Analysis of the intertester reliability between T1 and T2 demonstrated excellent values for flexion and extension in the two different positions. This suggests that flexion and extension strength measurements are tester independent. So for example, to evaluate an athlete’s progress during the season, the tests should not always be executed by the same tester. Analogous to the intratester reliability, the ICC values for intertester reliability were highest in the 30° position. The intertester reliability between T1 and the straps and T2 and the straps for extension in the neutral position was poor to fair. All values with the straps in the 30° flexion position were excellent. These results are important to take into practice. Both for intra- and intertester reliability, there was a higher agreement in the 30° position than in the neutral position. The 30° position was found easier to perform and maintain the test position according to the participants.

So we can conclude that the 30° flexion position is the most reliable position to measure flexion and extension force with HHD by a tester or by straps. Highly reliable measurements of trunk flexion and extension strength using HHD are only ensured using the same subject position with the same test method in pre- and post-measurements.

4.2 Validity
To evaluate the validity, the authors investigated the Pearson correlation coefficients between BioniX values and HHD values of day one by T1. The correlation coefficients were higher for the flexion tests than for the extension tests. In flexion the highest correlations were found between the HHD test in 0° and the BioniX test in 0° (0.823) and between the HHD test in 30° and the BioniX test in 30° (0.862). In extension, the HHD test in 30° showed higher correlation with both the BioniX in 0° and 30° (0.748 and 0.733 respectively) than the HHD extension test in 0° (0.633 and 0.559). Based on these results, it seems that the HHD flexion tests were better predictors for the BioniX tests than the HHD extension tests and that the HHD test in extension 0° was the worst predictor for the BioniX.

Some authors used cut off values when using correlation coefficients to determine the validity. When using these cut off values, the level of validity was determined as follows: correlation coefficients > 0.80 indicated high validity, values between 0.60 and 0.80 indicated good validity, values between
0.40 and 0.59 indicated moderate validity, and values < 0.40 indicated poor validity (20). When these cut off values were applied on the test results, the HHD test in flexion 30° and in flexion 0° were given high validity and the HHD tests in extension were given a good validity.

Secondly, eight simple linear regression analyses were done. The linear regression, which is an important method to evaluate the validity of a test, were good for all HHD flexion tests and HHD extension tests in 30°. This means that the results of the HHD tests are consistent, which is very important for field tests. For the HHD extension tests in 0°, linear regression was less good in comparison to the other tests which can indicate a lower validity and is less recommended to use in clinical practice.

At last, a comparison of means of HHD values of T1 on day one and BioniX was made to determine the validity. On average, the HHD underestimated absolute muscle strength in comparison to the BioniX. There were important differences between the results for HHD and BioniX that need to be considered. A possible explanation for this difference could be the difference in position of the subjects during the tests. In the HHD tests, the subjects laid prone or supine while the subjects stood upright during the BioniX tests. Because the aim of this study was to create a test which can be used easily in clinical practice, a lying position was chosen to test with the HHD. Furthermore, the fixation of the subjects was different. During the HHD tests, the subjects were fixated with two non-elastic belts around the legs and hips and the tester gave resistance with the HHD on the middle of the thorax. In the BioniX, the subjects were fixated on the level of the shoulders and ASIS. These factors could have influenced the subjects feeling and their generation of power. Also, the influence of gravity is different for the BioniX tests and the HHD tests. In the BioniX, only extension 30° is a muscle action against gravity. In HHD all measurements are against gravity. To investigate these differences between the results for the two devices, an EMG-study should be conducted in further investigations. By measuring the EMG activity of the muscles used during the HHD tests and the BioniX tests, a comparison can be made and further establish validity of HHD.

4.3 Differences in test positions

A comparison of the means was made both for HHD as for BioniX. The measured values tested in the 0° position were consistently lower than those measured in the 30° flexion position, except for the flexion test with the straps. The belt-resisted method requires less physical effort of the tester, therefore forces measured with a belt-stabilized HHD would reveal higher values than assessed manually, as previously reported for the knee and the hip (28, 29, 30, 31). In the present study, the
force measurements with the straps are lower than the ones with manual resistance applied by the tester. Therefore, stabilizing the HHD using a non-elastic belt may not be optimal for replacing the manual resistance applied by the tester in trunk flexion and extension strength measurements. However, this should be investigated in further studies.

4.4 Strengths and limitations

During our testing period, we experienced both some strengths and limitations. There were no drop-outs during the testing protocol. Furthermore, excellent intra- and intertester reliability was proven and validity was shown good. As far as the authors know, this study is a pioneer in examining both reliability and validity of HHD in trunk flexion or extension strength tests (21). Consequently, this testing procedure is based on studies using HHD in tests with extremities (30, 36). During the tests with the straps on day two, the testers assumed this tests were tester-independent. Tester-independency was not proved yet, so this should be examined before use in clinical practice. On both testing days, the subjects did not complete any warming-up, which can be of influence on the testing results. Furthermore, it was not possible to analyse intratester reliability for the tests with straps because this was only tested on the second day. Reliability of HHD can be depending on sex, weight, handgrip strength and strength of the tester (33, 34). In this study, both testers were male. Weight, handgrip strength and strength were not tested in advance. Further research has to be done to evaluate the influence of these factors. At last, the test was static and the lying test positions were not functional. Most of the daily motions and sport movements take place in different positions and are dynamic movements. Therefore, further investigations should focus on dynamic tests in functional positions.
5. Conclusion

Because of the recognized link between CS and lower extremity injuries in sports, reliable and valid CS tests are needed to identify athletes at risk (2). On the other hand there is a lack of tests which are proved to be reliable and/or valid to evaluate CS (2, 32). Most of the tests that have been developed evaluate CS, core endurance or postural control. The authors developed different tests to evaluate core strength which can easily be used in clinical practice. The trunk flexion and extension tests presented in this study measured by HHD have an excellent intra- and intertester reliability if measured by a tester. Furthermore, validity is excellent for flexion tests and extension tests in 30° degrees, but fair for the extension test in 0°. The results suggest that HHD used in a 30° flexion position offers a feasible, inexpensive and portable test to measure trunk strength in a healthy population. It underestimates the absolute strength both for flexion and extension compared to the BioniX, but it is a useful tool to assess quick and objective the physical function in the clinical setting: just a treatment table and a hand-held dynamometer are needed to conduct these CS tests. As a consequence, these tests can easily be added to a test battery which evaluates core strength, CS and postural control.
6. References


32. Waldhelm A. Assessment of core stability: developing practical models. 2011 May


35. Calders A. Nieuw, maar uniek in medische machinebouw. Industrie. 2010; 48-50

Abstract in lekentaal

Achtergrond en doelstellingen: Hand-held dynamometrie (HHD) is een veelgebruikte methode voor het meten van kracht in onderste en bovenste ledematen. Hiermee kan men op een eenvoudige manier de kracht weergeven van bewegingen. Het is een klein toestel waarmee je weerstand geeft tegen de beweging en deze meet de kracht in Newton. HHD is dan ook voor veel verschillende bewegingen gevalideerd. Deze methode werd echter nog niet toegepast om de kracht van de romp te meten. Het doel van deze studie was dan ook om a) de betrouwbaarheid te onderzoeken tussen twee testers (intertester) en de betrouwbaarheid te onderzoeken tussen twee testen van dezelfde test bij rompbuiging en rompstrekkings (intratester) vanuit twee testposities, b) deze twee posities onderling te vergelijken en c) de validiteit na te gaan door deze methode te vergelijken met een elektromechanische dynamometer ‘BioniX’, een gouden standaard om de kracht te bepalen van deze spieren.

Methode: Negenentwintig volwassenen (14 vrouwen en 15 mannen) namen deel aan deze studie. Maximale rompbuigings en –strekkings kracht werd gemeten in twee posities: liggen met 0° rompbuiging en liggen met 30° rompbuiging. Op dag één testte tester 1 (T1) door middel van HHD, gevolgd door dezelfde testen in de BioniX. Op dag twee werden dezelfde metingen met HHD herhaald door T1, tester 2 (T2) en door middel van fixatiegordel om de testpersonen te fixeren. Intratester betrouwbaarheid werden geëvalueerd door middel van de intraclass correlation coefficient (ICC), een berekening die werd uitgevoerd met behulp van een statistisch programma. Om de validiteit te bepalen werden de gemiddelde resultaten van de HHD en de BioniX onderling vergeleken (aan de hand van student’s t-test). Daarnaast werden ook de resultaten tussen de verschillende posities vergeleken (student’s t-test).

Resultaten: Intratester betrouwbaarheid was excellent voor buiging en strekking in beide posities (ICC = 0.802 – 0.965). Intertester betrouwbaarheid tussen T1 en T2 was in elke positie excellent. Intertester betrouwbaarheid tussen T1/T2 met de fixatiegordel varieerde van goed tot excellent behalve bij de strekkingstesten vanuit neutrale positie, hierbij werden ICC waarden zwak tot billijk bevonden (ICC = 0.389 – 0.541). Bij HHD waren alle gemiddelde scores van de testen vanuit 0° lager dan deze van de testen in 30° behalve voor de rompbuiging test met fixatiegordel. Deze verschillen waren niet altijd opvallend. Bij de BioniX waren de gemiddelde waarden van de testen in 0° telkens opvallend lager dan deze in 30°. De gemiddelde waarden van alle HHD testen waren opvallend lager dan deze van de BioniX.
Conclusie: Deze resultaten suggereren dat HHD vanuit de 30° rompbuiging een waardig, betaalbaar en draagbaar alternatief vormt voor het testen van rompbuiging en -strekking in een gezonde populatie. Deze methode onderschat de absolute kracht die behaald wordt in de BioniX, maar is een nuttige methode voor het snel en objectief meten van kracht in een klinische setting.
# Appendix

## Appendix 1: overview test procedure

<table>
<thead>
<tr>
<th>Day 1</th>
<th>7 days rest</th>
<th>Day 2</th>
</tr>
</thead>
</table>
| **Weighed and measured**  
HHD T1 (5 sec)  
Isometric flexion  
– 0°  
– 30°  
Isometric extension  
– 0°  
– 30°  
**15 minutes of rest**  
**BioniX tests**  
Isometric tests (5sec)  
– Flexion 0°  
– Flexion 30°  
– Extension 0°  
– Extension 30° |  | **Questionnaire**  
**Measurement of distance between**  
– Nippleline and ASIS  
– Angulus Inferior and PSIS  
**HHD T1 (5 sec)**  
Isometric flexion  
– 0°  
– 30°  
Isometric extension  
– 0°  
– 30°  
**Same HHD T2**  
**Same HHD straps** |

## Appendix 2: questionnaire day 2

<table>
<thead>
<tr>
<th>Questions</th>
<th>Answer possibilities</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Present musclesoreness or pain</td>
<td>Scale 0 to 10</td>
</tr>
<tr>
<td>2. Activity difference between the 2 testdays</td>
<td>Yes or no</td>
</tr>
<tr>
<td>3. Heavy activities one day before testday 2</td>
<td>Yes or no</td>
</tr>
</tbody>
</table>

## Appendix 3: HHD testing position

Figure A: neutral position trunk flexion
Figure B: 30° position trunk flexion

Figure C: neutral position trunk extension

Figure D: 30° trunk extension
Appendix 4: BioniX testing position

Figure A: neutral position in BioniX

Figure B: position 30° of flexion in BioniX
Appendix 5: Informatiebrief voor de deelnemers aan experimenten

Toestemmingsformulier

Ik, _________________________________________ heb het document “Informatiebrief voor de deelnemers aan experimenten” pagina 1 tot en met 5 gelezen en er een kopij van gekregen. Ik stem in met de inhoud van het document en stem ook in deel te nemen aan de studie.

Ik heb een kopij gekregen van dit ondertekende en gedateerde formulier voor “Toestemmingsformulier”. Ik heb uitleg gekregen over de aard, het doel, de duur, en de te voorziene effecten van de studie en over wat men van mij verwacht. Ik heb uitleg gekregen over de mogelijke risico’s en voordelen van de studie. Men heeft me de gelegenheid en voldoende tijd gegeven om vragen te stellen over de studie, en ik heb op al mijn vragen een bevredigend antwoord gekregen.

Ik stem ermee in om volledig samen te werken met de toeziende onderzoeker/arts. Ik zal hem/haar op de hoogte brengen als ik onverwachte of ongebruikelijke symptomen ervaar.

Men heeft mij ingelicht over het bestaan van een verzekeringpolis in geval er letsel zou ontstaan dat aan de studieprocedures is toe te schrijven.

Ik ben me ervan bewust dat deze studie werd goedgekeurd door een onafhankelijke Commissie voor Medische Ethiek verbonden aan het UZ Gent en dat deze studie zal uitgevoerd worden volgens de richtlijnen voor de goede klinische praktijk (ICH/GCP) en de verklaring van Helsinki, opgesteld ter bescherming van mensen deelnemend aan experimenten. Deze goedkeuring was in geen geval de aanzet om te beslissen om deel te nemen aan deze studie.

Ik mag me op elk ogenblik uit de studie terugtrekken zonder een reden voor deze beslissing op te geven en zonder dat dit op enigerlei wijze een invloed zal hebben op mijn verdere relatie met de onderzoeker/arts.

Men heeft mij ingelicht dat zowel persoonlijke gegevens als gegevens aangaande mijn gezondheid worden verwerkt en bewaard gedurende minstens 20 jaar. Ik stem hiermee in en ben op de hoogte dat ik recht heb op toegang en verbetering van deze gegevens. Aangezien deze gegevens verwerkt worden in het kader van medisch-wetenschappelijke doeleinden, begrijp ik dat de toegang tot mijn gegevens kan uitgesteld worden tot na beëindiging van het onderzoek. Indien ik toegang wil tot mijn gegevens, zal ik mij richten tot de toeziende onderzoeker/arts, die verantwoordelijk is voor de verwerking.

Ik ben bereid op vrijwillige basis deel te nemen aan deze studie.

Naam van de vrijwilliger: ____________________________________________

Datum: ____________________________________________________________

Handtekening:

Ik bevestig dat ik de aard, het doel, en de te voorziene effecten van de studie heb uitgelegd aan de bovenvermelde vrijwilliger.

De vrijwilliger stemde toe om deel te nemen door zijn/haar persoonlijk gedateerde handtekening te plaatsen.

Naam van de persoon die voorafgaande uitleg heeft gegeven: ____________________________________________

Datum: ____________________________________________________________

Handtekening
Bewijs van indiening bij het ethisch comité
The Ethics Committee is organised and operates according to the 'ICH Good Clinical Practice' rules.

The Ethics Committee stresses that approval of a study does not mean that the Committee accepts responsibility for, or guarantees, the accuracy or reliability of, the information contained in the report, reports to the government, etc. that are a result of this research.

In the framework of 'Good Clinical Practice', the pharmaceutical company and the authorities have the right to inspect the original data. The investigators have to ensure that the privacy of the subjects is respected.

The Ethics Committee stresses that it is the responsibility of the promoter to guarantee the confidentiality of the non-disclosure information forms with the Dutch documents.

None of the investigators involved in this study is a member of the Ethics Committee.

All members of the Ethics Committee have reviewed this project. (The list of the members is enclosed)

Namens het Ethisch Comité / On behalf of the Ethics Committee

Prof. dr. D. MATTHYS
Voorzitter / Chairman

CC: De heer T. VERSCHOORE - UZ Gent - Bimeira Clinics
    FAGG - Research & Development, Victor Hortaplain 40, postbus 40, 1080 Brussels
    Prof. dr. G. VANDERSTRAETEN
Advis voor monochrónische studie met als titel: Onderzoek naar core stability als risicofactor voor het ontwikkelen van letsels aan het onderste ligament: Een prospectieve studie. Scriptie Hanne Seru.

Belgisch Registratienummer: B6720261524283

Fase (Phase): NVT/NA

* Adviesaanvraagformulier dd. 19/03/2015 (volledig ontvangen dd. 25/03/2015)
* Begeleidende brief dd. 19/03/2015
* Diverses
  - Alle goedgekeurde documenten project 2014/0760

Advies werd gevraagd door:
Prof. dr. P. ROOSEN; hoofdonderzoeker

DIT ADVIES WORDT OPGENOMEN IN HET VERSLAG VAN DE VERSLAGDER VAN HET ETHISCH COMITÉ VAN 21/04/2015

Het Ethisch Comité werkt volgens "IC Good Clinical Practice"-regels

Het Ethisch Comité houdt er rekening met dat een gunstig advies met betrekking tot het Ethisch Comité de verantwoordelijkheid voor het onderzoek op zich neemt.6a6d600c-193b-41f9-8bc0-0b3c3a0f998e

Deze brief diende in het bijzonder om de ethische en juridische aspecten van de onderzoeksvoering in het kader van "Good Clinical Practice" te verduidelijken. De brief bevatte een schatting van de mogelijke risico's van het onderzoek en het effect op de deelnemers. De brief werd overhandigd aan de betrokken onderzoekers voor informatie en overleg. De brief was voldoende om de ethische en juridische aspecten van het onderzoek te verduidelijken.

Het Ethisch Comité besloot dat het onderzoek in het bijzonder diende te worden geëvalueerd op basis van de ethische en juridische aspecten van de onderzoeksvoering. De brief bevatte een beschrijving van de ethische en juridische aspecten van het onderzoek en het effect op de deelnemers. De brief was voldoende om de ethische en juridische aspecten van het onderzoek te verduidelijken.

Geen enkel onderwerp betrof erbij deze studie te lid van het Ethisch Comité.

Alle leden van het Ethisch Comité hebben dit project beoordeeld. (De ledenlijst is bijgevoegd)

Sofie Verdonckt
08/032 03 69
sofie.verdonckt@ugent.be
Contact
Secretariaat
TELEFOON
+32 (0)9 332 96 13
+32 (0)9 332 99 28
FAX
+32 (0)9 332 49 62
E-MAIL
ethisch.comite@ugent.be
Uw kenmerk
ONS KENMERK
2019/0295
Datum
26-mrt-15
Kopie
Zie "CC"

Vervolg blz. 2 van het adviestoetsformulier betreffende project EC UZG 2019/0295

* The Ethics Committee is organized and operates according to the WCM Good Clinical Practice rules.
* The Ethics Committee stresses that approval of a study does not mean that the Committee accepts responsibility for it. Moreover, please keep in mind that your opinion as investigator is presented in the publications, reports to the government, etc., they are a result of this research.
* In the framework of Good Clinical Practice, the pharmaceutical company and the authorities have the right to inspect the original data. The investigators have to ensure that the privacy of the subjects is respected.
* The Ethics Committee stresses that it is the responsibility of the promoter to guarantee the conformity of the non-dutch referred content forms with the Dutch documents.
* None of the investigators involved in this study is a member of the Ethics Committee.
* All members of the Ethics Committee have reviewed this project. (The list of the members is enclosed)

Namen het Ethisch Comité / On behalf of the Ethics Committee

Prof. Dr. D. Matthys
Voorzitter / Chairman

CC: De heer T. Verschoore - UZ Gent - Rimec Clinics
FAGQ - Research & Development, Victor Hortaoplein 40, postbus 40, 1060 Brussel
Prof. Dr. G. Vanderstraeten

Universtair Ziekenhuis Gent
De Pinte 185-B- 9000 Gent
www.uzgent.be

Sofie Vercoulere
09/332 03 89
sofie.vercoulere@uzgent.be
Universitair Ziekenhuis Gent

Afz. Commissie voor Medische Ethiek

REVAKI
3 B3
Prof. dr. Philip ROOSEN
ALHIER

CONTACT
Secretariaat
+32 (0)9 332 56 13
+32 (0)9 332 58 28

UW KENMERK
ONS KENMERK
2015/0294

DATUM
26-mei-15

KOPIE
Zie "CC"

BETREFT
Advies voor monocentrische studie met als titel:
"Onderzoek naar core stability als risicofactor voor de ontwikkeling van letsel aan het onderste lidmaat: Een prospectieve studie."
Scriptie Melanie Huysge

Belgisch Registratienummer: B670201524282

Fase (Phase): NV/TNA
* Adviesaanvraagformulier: dd. 19/03/2015
  (volledig ontvangen: dd. 23/03/2015)
* Begeleidende brief: dd. 19/03/2015
* Diverse
  Alle goedgekeurde documenten project 2014/0789

Advies werd gevraagd door:
Prof. dr. P. ROOSEN; Hoofdonderzoeker

BOVENVERMELDE DOCUMENTEN WERDEN DOOR HET ETHISCH COMITÉ BEOORDEELD. ER WERD EEN POSITIEF ADVIES GEGEVEN OVER DIET PROTOCOL OP 29/03/2015. INDIEN DE STUDIE NIET WERDT OPGESTART VOOR 25/03/2016, VERVALT HET ADVIES EN MOET HET PROJECT TERUSS INGEDIENDE WORDEN.

Voorzitter het onderzoek te starten dient contact te worden opgenomen met Bimetra Clinics (09/332 05 00).

THE ABOVE MENTIONED DOCUMENTS HAVE BEEN REVIEWED BY THE ETHICS COMMITTEE. A POSITIVE ADVICE WAS GIVEN FOR THIS PROTOCOL ON 29/03/2015. IN CASE THIS STUDY IS NOT STARTED BY 25/03/2016, THIS ADVICE WILL BE NO LONGER VALID AND THE PROJECT MUST BE RESUBMITTED.

Before initiating the study, please contact Bimetra Clinics (09/332 05 00).

DIT ADVIES Wordt OPGENOMEN IN HET VERSLAG VAN DE VERGADERING VAN HET ETHISCH COMITÉ VAN 21/04/2015

THESE ADVICE WILL APPEAR IN THE PROCEEDINGS OF THE MEETING OF THE ETHICS COMMITTEE OF 21/04/2015

Het Ethisch Comité beslist volgens "Good Clinical Practice"-regels:

* Het Ethisch Comité beoordeelt dat een genoeg aantal patiënten is beoordeeld dat de Comité de verraadbaarheid voor het onderzoek op zich weet. Bepaalde dient U in uw rapport dat het deelname als betaalt onderzoekers wordt voorkomen in publicaties, rapporten voor de overheid etc. die het resultaat zijn van dit onderzoek.

* Het advies van "Good Clinical Practice" moet de mogelijkheid beperken dat de gevorderden te lage en/of beperkte gegevens van de originele data. Dit verband dienen de onderzoekers ervoor te zorgen dat dit gebeurt zonder schending van de privacy van de proefpersonen.

* Het Ethisch Comité beoordeelt dat het deelnemen is dat deelnemers in dit geval voor de conformiteit van de onderzoeks- en toetseningsformulieren met de Nederlandse wetgeving dienen.

* Het advies van "Good Clinical Practice" moet worden gecensureerd in de gevorderden die deelnemers in dit geval voor de conformiteit van de onderzoeks- en toetseningsformulieren met de Nederlandse wetgeving dienen.

* Alle deelnemers aan dit onderzoek dienen dit project in te dienen.

Sofie Vercauteren
09/332 03 69
sofie.vercauteren@uzgent.be
Vervolg blz. 2 van het adviesformulier betreffende project EC UZG 2015/0294

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* In the framework of 'Good Clinical Practice', the pharmaceutical company and the authorities have the right to inspect the original data.
* The investigators have to assure that the privacy of the subjects is respected.
* The Ethics Committee stresses that it is the responsibility of the promoter to guarantee the conformity of the non-Dutch informed consent forms with the Dutch documents.
* None of the investigators involved in this study are a member of the Ethics Committee.
* All members of the Ethics Committee have reviewed this project (The list of the members is enclosed)

Namens het Ethical Comité / On behalf of the Ethics Committee

Prof. dr. D. MATTHYS
Voorzitter / Chairman

CC: Da heer T. VERSCHOORE - UZ Gent - Bieneva Clinics
FAGG - Research & Development: Victor Hortapers 40, postbus 40 1000 Brussel
Prof. dr. G. VANDERSTRAETEN

Universitair Ziekenhuis Gent
De Pintelaan 185, B- 9000 Gent
www.uzgent.be

Sofie Vercoutere
09/332 33 89
sofie.vercoutere@uzgent.be