Maximum muscle force measurement in infants and toddlers

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Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON30704

Source
ToetsingOnline

Brief title
Infant-Muscle-Force Measurement (IMFM)

Condition

- Other condition
- Muscle disorders
- Neuromuscular disorders

Synonym
decreased muscle force

Health condition

aangeboren spieraandoeningen

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: children, Infant, Measurement, Muscle-force

Outcome measures

Primary outcome

Statistical analysis

To answer the research questions the IMF maximum muscle force in Newton out of three measurements and the raw and normalized scores for the AIMS will be calculated for each age group.

· To test the intrarater reliability the correlation between IMF-test-1 (at the beginning) and IMF-test-2 (at the end) performed by the same tester will be calculated for each different age group. To test the interrater reliability the correlation between IMF-test-1 and IMF-test-2 performed by two different testers will be calculated for each different age group.

· To test the construct validity the correlation between IMF and motor development test (AIMS) will be calculated for each different age group.

· Reference values will be calculated using means and standard deviations for each different age group. If necessary different values will be used for boys and girls.

Secondary outcome

not relevant

Study description

Background summary

BACKGROUND
There is no objective method to measure muscle force in young children. Such an objective method will be beneficial for clinical practice. Objective muscle force measurements provide the pediatric physical therapist with information about the role of muscle force in functional motor performance in different circumstances. In longitudinal studies and clinical trials such objective measurements have to be comparable between different testers and are necessary to document muscle force changes over time related to growth and development, the effects of therapeutic interventions, or related to muscular diseases. In young children, like in children with the Prader-Willi Syndrome (PWS), muscle force impairments are strongly related to functional motor development and limitations in activities of daily living. Because there is no standard method, nowadays therapists establish muscle weakness on the base of systematically assessment of motor skills. The problem with this method is that skill acquisition is not only dependent of muscle force but also of age and growth. Therefore an objective muscle force measurement is more accurately, to examine the effect of muscle weakness on functional skill performance and to identify how much force is necessary to perform specific age-related functional activities. This information is necessary to get insight in the relationship between muscle force and functional skills in healthy children and children with neuromuscular problems.
The department of pediatric physiotherapy of the UMC St Radboud Nijmegen has started, in addition to the Dutch National Growth Hormone Study (DNGHS), the Motor Training in PWS (MoTraP) research project. The MoTraP study investigates in an infancy group (0-3 years) if growth hormone treatment leads to better profit of physiotherapy treatment. The intervention focuses on the increment of muscle mass and muscle force related to motor skill acquisition. Various motor tests are available and these are used to determine the motor development of the child. However, these tests are a bit rough to test children with PWS, because these tests only allow scoring if a child can or cannot do a specific age-related skill. These tests do not give insight in the increment of muscle force, the relationship between muscle mass and muscle force increment and skill acquisition. Therefore it is necessary to look more accurately to changes in muscle force, because of the expected relationship between muscle mass, muscle force and skill acquisition.

Muscle force measurements
There is no standard method for young children to measure muscle force. Only a few studies included children younger than the age of five, when measuring muscle force (1-3). Previous investigators concluded that it is not possible to measure very young children with the present measurement methods,

because of their activity level, shorter attention span, wariness of strangers, and inconsistent performance in unfamiliar environments (3-5). Furthermore they often have more inconvenience adjusting to a testing situation than older children, and their normal, but challenging behaviors, can influence the test results.
Muscle force can be estimated and measured using different methods, ranging from observation without equipment, such as videotaping, to laboratory examinations with isokinetic instruments. In clinical practice, the two most common methods are manual muscle testing (MMT) scored by the Medical Research Council (MRC) and hand-held dynamometry (HHD). Both methods are isometric muscle strength testing methods. Standard MMT techniques are based on the patients* ability to move against gravity and hold against the examiners resistance. However, the sensitivity of detecting changes in muscle strength with MMT is poor because it produces ordinal scale data, ranging from 0 (no observable contraction) to 5 (normal movements possible against manual resistance). Because MMT is unsuitable for detecting small changes in strength and therefore in patient populations the HHD-method is recommended. The HHD-method allows a simultaneous quantitative and objective assessment of the strength of the muscular contraction through the use of a pressure sensor. An examiner holds the dynamometer and applies tension against the subject (the break test) or holds the dynamometer stationary while the subject exerts a maximal force against it (the make test). The pressure sensor is positioned so that the force exerted by the selected muscle during contraction is transmitted indirectly to the pressure sensor. The HHD-method reproduces the muscle force in Newton. There are studies available that establish reference values of maximum isometric force obtained with a HHD in normal children aged 4-16 years (6). However, no studies were found that measured young children from 0-3 years old. This is probably because it is not possible to give instructions to young children and it is not possible to provoke an isometric contraction in a discrete movement direction in very young children.

Study objective

Main objective
Because this study will include young children (0-3 years old) the challenge is to measure isometric muscle force adjusted to their natural behavior. From 4 months old a child can pull a toy towards himself. Therefore we want to use this activity to provoke a maximum muscle force activity. At the moment a child grabs a toy and pulls it towards himself the examiner will give counterforce in the contrary direction. As a result of synchronizing the muscle force between the child and the examiner, the child will reach his maximum muscle force. The department of pediatric physiotherapy developed a prototype of an Infant-Muscle-Force meter (IMF meter), which measures the muscle force using a Load Cell placed under the chair of the child. In a pilot study with this IMF meter it was found that it is possible to induce and register the maximum muscle force of children and toddlers during such a pulling task. This study will investigate whether it is possible to measure

objectively the muscle force in 0-3 years old children with the IMF-meter in such a way that reference values can be used in clinical decision-making. Therefore we will test the reliability and construct validity of the IMF meter in different age groups (6, 9, 12, 18, 24, 30 and 36 months-old children). To determine the reliability the intrarater en interrater reliability will be tested and to determine the construct validity the IMF meter will be compared to a standard motor task: the Alberta Infant Motor Scale (AIMS). We expect a positive correlation between the IMF meter and the AIMS, because of the expected relationship between muscle force and motor development. However it is not possible to estimate beforehand the strength of correlation, because there are no reference values available about this relationship. If the reliability and construct validity of the IMF meter is positive, the IMF values obtained in the different age group will be used as reference values for the IMF meter.

Study design

Instruments
Infant-Muscle-Force meter (IMF meter). The IMF meter takes use of a Load Cell (LECB-50), with a high pass filter of 30 Hz, to register pull and push forces. The load cell is part of a platform, above the platform a child chair is installed (Figure 1). With the IMF meter it is possible to induce and register the maximum muscle force of infants and toddlers during a pulling task. The IMF meter takes use of the DAS-Wizard computer program. DAS-Wizard is an Add-in for Excel that places measurements, with a sample frequency of 10 Hz, directly into the cells of an Excel worksheet. With this information it is possible to detect the maximum muscle force that the child can deliver. To exclude other circumstances that can cause a peak value, for example chair movement, the IMF data will be analyzed synchronous with a videotape of the experiment.
Alberta Infant Motor Scale (AIMS). The AIMS is a standard reliable and valid motor test (7) which describes in 58 developmental steps motor skill acquisition in four different positions: prone, supine, sitting and standing. Within every position the examiner scores the least and most mature developmental motor step present in the motor repertoire of the child. The range between the least and most mature motor step is called the motor-window. The total score of the AIMS is the summation of all the motor steps preceding the motor-window (the motor steps the child has outgrown) and all motor steps present in the current motor repertoire within the motor-window.

Procedure
For an overview of the measurements see Table 1. Before starting with the measurements height, weight, and age of each child will be recorded. First we will measure the muscle force with the IMF-meter, followed by the AIMS. At the end of the test muscle force will again be measured with the IMF meter.

Table 1: Overview of the measurments.
Time Measurements

5 min Introduction/Acquaintance/ length and weigth
5 min IMF-test-1*- Pulling three times
15 min AIMS- Prone- Supine- Sitting- Standing
5 min IMF-test-2*- Pulling three times

Total 30 min
* IMF-test-1 and IMF-test 2 will be performed counterbalanced by the same or different tester to test intrarater en interrater reliability.

Two trained examiners will participate in this study. The subjects will be randomly assigned to the examiners (Figure 2). For the intrarater reliability subjects will be tested two times with the IMF meter, at the beginning and at the end of the test, by the same tester. For the interrater reliability subjects will be tested two times with the IMF meter by two different examiners. One examiner will measure the muscle force at the beginning of the test; the other examiner will measure the muscle force at the end of the test. The examiner who will start with the first measurement is counterbalanced.

During the measurements with the IMF meter the child will be seated on a small chair, adapted for his size, with his feet several centimeters above the floor. The upper body will be stabilized with a wide cloth strap that will be wrapped around the child and chair. Children will be videotaped during the session using a camera for a side view, so it is possible to analyze IMF data synchronous with the videotape. The general idea of the IMF-meter is to provoke a pulling activity from the child. To do so, the examiner, facing the child, will try to find a toy the child likes. We expect the likelihood of the toy is conditional to evoke the maximum muscle force. From that moment the game will begin in which the child will pull the toy towards himself and the examiner gives counterforce. As a result of synchronizing the muscle force between the child and the examiner, the child will reach his maximum muscle force. This procedure will be repeated three times, the highest value will be considered as the maximum force. This value will be used, so the influence of practice and learning during the actual data collection can be excluded. After the first IMF measurements the child has to perform the AIMS, according to standardized procedures. At the end of the test the muscle force will be measured for the second time with the IMF meter. The total duration of the test will be around half on hour.

Study burden and risks

The children will be measured during activities, which are part of their natural behavior. There are no specific risk factors.
Extend of the burden for the child is minimal. Extend of the burden for the parents is limited to the time investment. The parents are totally free to

choose for participation so the burden is low.

Contacts

Public
Universitair Medisch Centrum Sint Radboud

Geert Grooteplein 10
6500 HB Nijmegen
NL
Scientific
Universitair Medisch Centrum Sint Radboud

Geert Grooteplein 10
6500 HB Nijmegen
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Children (2-11 years)

Inclusion criteria

Healthy, normal children between 0 and 3 years old, with written informed consent.

Exclusion criteria

Preterm and children with known health problems will be excluded.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2007
Enrollment:	200
Type:	Anticipated

Ethics review

Approved WMO

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL16274.091.07