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Is it possible to distinguish different components of ankle joint stiffness in spastic subjects using a portable device?

Submission date
09/03/2017

Recruitment status
No longer recruiting

Registration date
16/03/2017

Overall study status
Completed

Last Edited
26/11/2020

Condition category
Musculoskeletal Diseases

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Cerebral Palsy (CP) is a general term that describes a number of neurological conditions that affect movement and coordination. CP can be caused by complications during pregnancy or birth that then causes brain damage. People with CP often develop spasticity. Spasticity is an increased resistance with exaggerated muscle activity when the muscle is stretched (reflex mediated stiffness). Spasticity is caused by a reflex and is controlled by the brain. Another symptom of patients with CP is increased stiffness when a joint is moved due to changes in the muscle. These two symptoms need different treatments; however it is hard to differentiate between them. The standard way to assess spasticity is usually based on a subjective score where the therapist ranks the resistance felt when moving the joint. With this method, it is difficult to separate the resistance coming from muscle spasticity from the resistance related to changes in muscles, tendons or connective tissue. There are now hand-held devices that can be used to as an objective method to measure joint stiffness and reflect mediated stiffness (spasticity). This device combines dynamometer (measures force), electromyography (EMG) (records electrical activity of the muscles), accelerometer (measures the speed of the body movement) and gyroscope (measures the angle of the movement). The aim of this study is to investigate the validity and reliability of a hand-held device.

Who can participate?
Healthy adults (age 18 or over) with no history of neurological disease and adults (age 18 or over) with cerebral palsy (CP), who did not receive anti-spastic treatment 12 months before the study.

What does the study involve?
Participants are allocated to one of two groups. The first group consists of participants with CP. They attend one 30 minute test session where a portable device is attached to the participant's foot. A clinician then performs five slow stretches of the ankle joint and five fast stretches, while the device measures acceleration (speed), angle, muscle activity and force during the movement. Those in the second group undergo six test sessions (all in one day) using the hand-held device. First, participants wear either the hand-held device or a stationary dynamometer and perform

slow and fast stretches. Participants are then seated in a stationary dynamometer, which automatically stretches the ankle joint at a slow speed. This is done to compare the measurements from the hand-held device with the standard measurements from the stationary dynamometer. To see if the hand-held device is capable of measuring stretch reflexes, participants are also assessed with the hand-held device before and during ischemia (blocking nerve impulses). This involves placing a blood pressure cuff above the knee and inflating it to around 240 mmHg. The total duration of the test sessions for the healthy participants is around three hours.

What are the possible benefits and risks of participating?
There are no notable benefits or risks with participating.

Where is the study run from?
Elsass Institute (Denmark)

When is the study starting and how long is it expected to run for?
January 2011 to July 2014

Who is funding the study?
1. Elsass Foundation (Denmark)
2. Association of Danish Physiotherapists (Denmark)

Who is the main contact?
Mathilde Kofoed-Hansen
mkh@movotec.dk

Contact information

Type(s)
Public

Contact name
Miss Mathilde Kofoed-Hansen

ORCID ID
http://orcid.org/0000-0002-1364-795X

Contact details
Elsass Institute
Holmegaardsvej 28
Charlottenlund
Denmark
2920

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Distinguishing passive and reflex-mediated ankle joint stiffness in adults with cerebral palsy using a portable device

Study objectives
The hand-held device may be able to adequately distinguish passive and reflex mediated ankle joint stiffness in an objective manner and this method is both valid and reliable.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of Copenhagen Denmark, 06/06/2011, ref: H-4-2012-107

Study design
Observational cross-sectional case-control reliability study

Primary study design
Observational

Secondary study design
Case-control study

Study setting(s)
Other

Study type(s)
Other

Participant information sheet
Not available in web format, please use contact details to request a participant information sheet.

Health condition(s) or problem(s) studied
Cerebral Palsy (CP)

Interventions
Both healthy adults and adults with Cerebral Palsy (CP) are included in this study. Participants are allocated to one of two groups.

Group 1 Participants with CP:
Participants in this group attend one test session. The total duration of this session is 30 minutes. The test session consists of measuring passive and reflex mediated stiffness in the

ankle joint plantar flexors by a hand-held device attached under the foot. The device contains a dynamometer, electromyography, accelerometer and a gyroscope. An experienced clinician performs slow stretches of the ankle joint from a plantar flexed position. Afterwards, fast stretches above the stretch reflex threshold are applied. One test session consists of five slow stretches and five fast stretches of each ankle joint. The purpose of this test session is to evaluate whether the hand-held device could evaluate and differentiate the passive ankle joint stiffness in subjects with CP compared to the population of healthy subjects.

Group 2 Healthy Participants:
Those in group two are allocated to a reliability study to investigate the reliability and reproducibility of the hand-held device. Each participant undergoes six test sessions with the hand-held device. Three different clinicians (raters) complete two test sessions each on the same participant. This is done for evaluation of both inter-rater and intra-rater reliability of the hand-held device.

After this, those in group two are seated in a stationary dynamometer where ten stretches of the ankle joint are automatically applied at a slow velocity. The purpose of this session is to investigate the validity of the measurements of passive joint torque obtained with the hand-held device compared to golden standard measurements of passive joint torque obtained using a stationary dynamometer.

To evaluate the validity of measuring reflex mediated joint stiffness (stretch reflex) with the hand-held device, five of the healthy participants are furthermore assessed both before and during ischemia. Ischemic nerve blockade of the tibial nerve has previously shown to abolish the stretch reflex. Ischemia of the lower leg is induced by placing a blood pressure cuff above the knee and inflating it to around 240 mmHg.

For those in group two, the total duration of the test sessions is approximately 3 hours. All test sessions are performed on the same day for each participant.

Intervention Type
Device

Primary outcome measure
1. Intra- and inter-rater reliability of slow and fast stretches are measured using the hand-held device at baseline
2. Validity of passive ankle joint stiffness is measured comparing the hand-held device compared to the golden standard stationary dynamometer at baseline
3. Differentiation of passive ankle joint stiffness between healthy subjects and subjects with CP is measured using the hand-held device at baseline

Secondary outcome measures
Velocity dependent contribution to passive stiffness is assessed using the hand-held device before and during ischemic nerve block

Overall study start date
03/01/2011

Completion date
08/07/2014

Eligibility

Key inclusion criteria
Healthy volunteer:
Aged 18 or older

Intervention group:
1. Diagnosed with CP
2. Aged 18 or older

Participant type(s)
Mixed

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
N=18

Total final enrolment
25

Key exclusion criteria
1. History of a neurological disease
2. Fracture in lower limbs
3. Treatment with anti-spastic medication within 12 months prior to the inclusion of the study

Date of first enrolment
01/04/2014

Date of final enrolment
01/05/2014

Locations

Countries of recruitment
Denmark

Study participating centre
Elsass Institute
Holmegaardsvej 28
Charlottenlund

Denmark
2920

Sponsor information

Organisation
Elsass Institute

Sponsor details
Holmegaardsvej 28
Charlottenlund
Denmark
2920

Sponsor type
Research organisation

ROR
https://ror.org/04jck5r17

Funder(s)

Funder type
Charity

Funder Name
Elsass Foundation

Funder Name
Danske Fysioterapeuter

Alternative Name(s)
Association of Danish Physiotherapists, The Association of Danish Physiotherapists

Funding Body Type
Private sector organisation

Funding Body Subtype
Associations and societies (private and public)

Location
Denmark

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
01/06/2017

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository at the research site Elsass Institute. The data is expected to be made available after publication.

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/09/2018	26/11/2020	Yes	No