Myoton. Validity, reliability and the sensitivity to change in dementia patients with paratonia.

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Determine the reliability, validity and the sensitivity to change of the MYOTON Handheld Digital Palpation Device for measuring the severity of paratonia in patients with dementia and paratonia .Research questions are:(1) What is the validity of the...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Muscle disorders
Study type	Observational non invasive

Summary

ID

NL-OMON42322

Source
ToetsingOnline

Brief title
MYOPAR

Condition

- Muscle disorders
- Movement disorders (incl parkinsonism)
- Dementia and amnestic conditions

Synonym
Paratonia/ Muscle stiffness

Research involving
Human

Sponsors and support

Primary sponsor: Hanzehogeschool

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: Clinimetric properties, Dementia, Myoton, Paratonia

Outcome measures

Primary outcome

Primary outcomes:

-Muscle tone, elasticity, creep, stiffness, mechanical stress relaxation

assessed with the Myoton

-Muscle tone/paratonia severity assessed with the Modified Ashworth Scale

-Muscle tone and stiffness assessed by palpation of the muscles

Secondary outcome

The presence or absence of paratonia assessed with the Paratonia Assessment

Instrument.

Study description

Background summary

Muscle hypertonia, movement stiffness and loss of elasticity are phenomena often seen in patients with dementia. One of the causes of movement stiffness is paratonia. When measuring the presence or absence of Paratonia, the Paratonia Assessment Instrument (PAI) is a reliable instrument and the golden standard for diagnosing paratonia. The severity of paratonia is scored by using the Modified Ashworth Scale (MAS). In clinical settings the MAS is the worldwide standard as a rating scale to measure abnormality in tone or the resistance to passive movements. Because the assessor has to judge the muscle tone by the perceived resistance during passive movement, the measurement is prone to subjectivity and extensive clinical experience is necessary for the MAS to become reliable. In assessing resistance during passive movement as with the MAS, it remains unclear which of the muscle properties such as tone, elasticity, creep, stiffness or mechanical stress relaxation are perceived by the assessor. For assessing and evaluating therapeutic interventions objective

measurements of muscle properties are required. New measurements, such as the MYOTON Handheld Digital Palpation Device, were developed and showed to be more sensitive and precise than the MAS to quantify muscle properties. The myotonometer has been validated in patients with stroke and upper motoneuron disorders. Also it has proven a reliable measurement in patients with stroke, Parkinson*s disease, in children with cerebral palsy and healthy subjects. However, the validity and reliability of the myotonometer has yet to be investigated in patients with paratonia and dementia.
This study aims to determine the concurrent validity against the MAS, criterion validity against the PAI, the reliability (inter and intra) and sensitivity for change of the Myoton Handheld Digital Palpation Device in dementia patients with paratonia

Study objective

Determine the reliability, validity and the sensitivity to change of the MYOTON Handheld Digital Palpation Device for measuring the severity of paratonia in patients with dementia and paratonia .

Research questions are:
(1) What is the validity of the MYOTON in measuring severity of Paratonia ?
(2) Which of the MYOTON measured muscle properties (tone, elasticity, creep, stiffness, mechanical stress relaxation) correlate strong with Paratonia ?
(3) Is the MYOTON reliable when repeating the measurement by another assessor on the same session (inter-observer reliability)?
(4) Is the MYOTON reliable or reproducible over time (i.e intra-observer reliability and absolute measurement error)?
(5) Is the MYOTON sensitive to change for paratonia severity after 6 months?

Study design

A longitudinal observational cohort study with a 6-months follow-up in 168 patients with dementia.
A total of 4 assessments will be performed at home, in day-care centres and nursing homes; at baseline 3 assessment (T0 by assessor 1, T0 by assessor 2 and 30 minutes later a second T0 by assessor 1), and after 6 months 1 assessment (T1 by assessor 1).

Because the incidence and severity of paratonia increases with the progression of the dementia, we propose a cohort with three subgroups (1: early stage dementia, 2: moderate stage dementia and 3: severe stage dementia).

Study burden and risks

Paratonia is a progressive form of hypertonia and only present in patients with dementia. For this reason, this study regarding paratonia and the Myoton

validity and reliability can only take place with patients with an established diagnosis of dementia. Earlier research showed that in early stage dementia the prevalence of paratonia is 34.8% and the 1-year incidence is 38.3%. Patiënts with early stage dementia live at home or are visiting day-care facilities with guidance of a casemanager. This makes this settings suitable to include dementia patients with and without paratonia. Prevalence of paratonia in later stage dementia is up to 90- 100%. Later stage dementia patiënts often live in nursing homes. There are no risks involved for the participants. Assessing muscle tone and paratonia is often part of usual assessment. Measurement with the Myoton only takes a few seconds and is painless and non-invasive.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

- Community dwelling dementia patients with an established diagnosis according to the DSM IV/DSM V criteria and a GDS score of 2,3 or 4 (= Early stage dementia)
- Institutionalized dementia patients with an established diagnosis according to the DSM IV/DSM V criteria and a GDS score of 5 or 6 (=Moderate stage dementia)
- Institutionalized dementia patients with an established diagnosis according to the DSM IV/DSM Vcriteria and a GDS score of 7 (= Severe stage dementia)
(The GDS is a 7-point scale indicating the severity of cognitive and functional decline in dementia with 1 No subjective complaints of memory deficits, 2 Subjective complaints, 3 Earliest clear-cut deficits, 4 Clear-cut deficits, 5 Patient can no longer survive without some assistance, 6 Largely unaware of all recent events and require assistance with activities of daily living, 7 Basic psychomotor skills and verbal ability are lost and require assistance in toileting and feeding).[
- Signed informed or proxy consent

Exclusion criteria

- Unstable health due to an interfering comorbidity.
- Using first generation psychotropic drugs, as these drugs can possibly mimic paratonic rigidity

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-04-2016
Enrollment:	168
Type:	Actual

Ethics review

Approved WMO Date:	03-12-2015
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Groningen (Groningen)

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	NL54144.042.15

Study results

Date completed:	10-03-2017
Actual enrolment:	168