Pathofysiology of postural instability in patients with distal and proximal myopathy

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To determine the contribution of proximal or distal muscle weakness to perturbations of stance induced by posturography.

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

Summary

ID

NL-OMON30142

Source
ToetsingOnline

Brief title
Balance in myopathy

Condition

- Muscle disorders

Synonym
Distal or proximal myopathy, muscle diseases

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: collectebusfondsen

Intervention

Keyword: Balance, Myopathy, Posturography

Outcome measures

Primary outcome

Balance in myopathy patients compared to healthy controls during external perturbations of the platform (expressed in Center of Mass displacement).

Prediction:

Proximal myopathy patients will have greatest instability for roll perturbations. Distal myopathy patients will have greatest instability for pitch perturbations.

Secondary outcome

1 Limb, pelvis, and trunk movements from 18 different sensor locations, measured during perturbations of the platform in patients with myopathy compared to healthy controls.

Prediction:

Instability on the platform is associated with abnormal knee, pelvis and lower trunk movements in patients with a proximal weakness and associated with abnormal ankle movements in patients with a distal weakness.

2 Muscle activity of ten muscles during perturbations of the platform, measured with surface electromyography.

Prediction:

Instability is associated with decreased amplitudes of proximal (trunk, hip)

muscles in proximal myopathy and with decreased amplitudes of distal (lower

leg) muscles in distal myopathy patients.

Study description

Background summary

Falling tendency in patients with myopathy is a common problem that is not only the cause of mild or severe injuries, but also of fear of falling and therefore a decreased activity level; the latter causing social isolation, decreased fitness, increased cardiovascular complications and in a higher mortality. Although epidemiologic studies implie that muscle weakness (myopathy) is associated with falling tendency, the exact pathofysiology is unknown. Insight in this pathofysiology would give more possibilities for treatment of falling tendency in these patients.
Our assumption is that falls are partially caused by a decreased ability to maintain balance during external perturbations. Especially patients with a proximal weakness would have problems with maintaining their balance, because hip and trunk movements are especially important during balance corrections after external perturbations. Although ankle movements are of less importance during correction after external perturbations, they play an important role in stance balance. Patients with a distal weakness might have problems correcting their balance because of their unability to correct their balance through ankle movements. Proximal myopathy patients might fail in correcting their balance, because trunk and hip movements are limited.

Study objective

To determine the contribution of proximal or distal muscle weakness to perturbations of stance induced by posturography.

Study design

This study is performed at the laboratorium for neuro-otology in the University Hospital in Basel, Switserland. The subjects are tested with multidirectional dynamic posturography and multisegmental motion analyses.
Subjects' balance is briefly measured during quiet stance with two pairs of gyrometers and one pair of accelometers around pelvis, trunk and head. Subsequently, the subjects are asked to stand on a moving platform that

perturbates in eight different directions (0°, 45°, 90°, 135°, 180°, 225°, 270° en 315°). Each direction is repeated ten times in an unpredictable order and with different intervals. Balance is measured objectively through the forceplatform (center of mass); muscle activity during perturbations is measured through EMG of 10 muscles. Furthermore, motion is analysed through infrared sensors placed at 18 spots on the extremities and trunk of the patient. During the perturbations two assistents stand next to the subject to help in case balance is lost and subjects can grap themselves with the handholds next to the platform. This protocol has been identically used in several earlier studies and is therefore sufficiently validated.

Study burden and risks

Patients are screened at the out-patients clinic of Neurology, to determine the extent of their muscle weakness and their suitability for the study. Furthermore, subjects are asked to fill out a questionnairy according their medical history and balance problems and to perform balance testing during quiet stance.
Subjects come to the university hospital in Basel, Switserland. Tests will be done on the second day and return journey is plannend on the third day of stay. All expenses are compensated.

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

Symmetrical proximal myopathy
Symmetrical distal myopathy

Exclusion criteria

Other disorders or medication that could influence balance control.

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-10-2006
Enrollment:	40
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	NL12922.091.06