MUPPET; Motor Unit and muscle strength changes in PostPolio syndrome, Evaluation after Ten years.

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To evaluate the long term changes in quadriceps muscle function in patients with PPS in comparison with control subjects. To correlate changes in muscle strength, functioning and symptoms with changes in motor unit size. To evaluate long-term...

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

Summary

ID

NL-OMON34659

Source
ToetsingOnline

Brief title
MUPPET

Condition

- Neuromuscular disorders

Synonym
Postpoliomyelitis Syndrome, PPS

Research involving
Human

Sponsors and support

Primary sponsor: Academisch Medisch Centrum
Source(s) of monetary or material Support: Prinses Beatrix Fonds

Intervention

Keyword: follow-up studies, motor neurons, muscle strength, postpoliomyelitis syndrome

Outcome measures

Primary outcome

Changes in maximal quadriceps strength and motor unit size since baseline

measurements 10 years ago.

Secondary outcome

Secondary parameters are changes in walking capacity, daily walking activity,

physical functioning, fatigue and additional motor unit characteristics.

Study description

Background summary

New muscle weakness is a frequent complaint among patients with Postpoliomyelitis Syndrome (PPS).Currently, there is contradictory evidence as to the rate of progression and cause of muscle weakness in post-polio syndrome. High-quality long term studies are scarce and although they have looked at changes in symptomatic patients they did not focus on changes in symptomatic muscles. For a better understanding of the pathophysiology and progression of muscle weakness in PPS, changes in motor units and muscle strength of large symptomatic muscles important for physical functioning need to be studied. In 1999 we investigated motor unit characteristics and muscle strength of symptomatic quadriceps muscles in 60 patients with post polio syndrome (PPS) and 20 healthy control subjects. Investigating changes in muscle strength and motor units in this cohort after 10 years will provide unique data on long-term changes in neuromuscular function in PPS that will contribute to a better understanding of the progression and pathophysiology of PPS.
The hypotheses are as follows: 1) muscle strength and motor unit size of symptomatic quadriceps muscles decline in post-polio syndrome patients at a faster rate than in age-and sex-matched control subjects; 2) a decline in motor unit size is associated with a decline in muscle strength and functional abilities and an increase in symptoms of PPS; 3) motor unit characteristics besides size will show more long term changes associated with dysfunction in PPS patients than in controls.

Study objective

To evaluate the long term changes in quadriceps muscle function in patients with PPS in comparison with control subjects. To correlate changes in muscle strength, functioning and symptoms with changes in motor unit size. To evaluate long-term changes in a variety of motor unit characteristics other than size.

Study design

Prospective cohort study. Long term follow-up.

Study burden and risks

There is no direct benefit to the participants of the study. Possible burden can be the time invested (2 visits, in total 3-4 hours, travelling to Amsterdam and Nijmegen, possibly getting muscle soreness after the muscle strength tests and possibly finding the electrical stimulation test unpleasant. These complaints, that can be caused by the testing procedure, are all temporary and none are harmful in the long-term. There are no specific risks associated with the study.

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

(1) All PPS subjects who participated in the trial by Horemans et al in 1999-2000*
(2) All controls who participated in the study described by Drost et al in the same period**;*
Horemans HL, Nollet F, Beelen A et al. Pyridostigmine in postpolio syndrome: no decline in fatigue and limited functional improvement. J Neurol Neurosurg Psychiatry. 2003;74:1655-1661
**Drost G, Stegeman DF, Schillings ML et al. Motor unit characteristics in healthy subjects and those with postpoliomyelitis syndrome: a high-density surface EMG study. Muscle Nerve. 2004;30:269-276.

Exclusion criteria

All participants of the trials of Horemans et al and Drost et al are eligible for participation unless they suffer from:
(1) Legal incompetence (incapacity), e.g. due to dementia
(2) Motor neuron disease or neurological disease that affects voluntary control of the quadriceps muscle under investigation.

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:	Basic science

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	12-07-2010
Enrollment:	80
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL31665.018.10