Fatigability in SMA: validity and reproducibility of tests.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON29501

Source
Nationaal Trial Register

Health condition

SMA
Spinal Muscular Atrophy
Fatigability

Sponsors and support

Primary sponsor: University Medical Center Utrecht
Source(s) of monetary or material Support: Stichting Spieren voor Spieren

Intervention

Outcome measures

Primary outcome

1) Reproducibility of fatigability tests (reliability (ICC) , measurement error (ME)

2) Construct Validity

- content validity between fatigability tests,perceived fatigue and peripheral muscle fatigue: Pearson/Spearman Correlation Coefficient

- convergent validity between fatigability tests (endurance time and delta muscle strength values) and nerve conduction study (delta compound muscle action potential) : Pearson/Spearman Correlation Coefficient

- convergent validity between fatigability tests (endurance time and delta muscle strength values), perceived fatigue (Borg scores and fatigue questionnaires) and peripheral muscle fatigue (EMG registration; Root Mean Square amplitude muscles arms/legs/respiratory)

- discriminative validity between fatigability tests SMA patients, healthy control group and patient controle group: Analysis of Variance (ANOVA)

Secondary outcome

Feasibility parameters

- measurement completion

- acceptability

- perceived burden

Study description

Background summary

The objective of this study is to develop reproducible and valid outcome measures for fatigability in patients with Spinal Muscular Atrophy. Recently, our research group demonstrated dysfunction of the neuromuscular junction in 50% of SMA-patients. The association between neuromuscular junction dysfunction and fatigability in SMA patients remains unclear. The psychometric properties of two newly developed fatigability tests will be investigated in SMA patients and healthy and patient control groups and the association between fatigability and neuromuscular function dysfunction in SMA patients will be studied The development of appropriate outcome measures for fatigability will give more insight in fatigability and the role of the neuromuscular junction in SMA patients and will contribute to the design of pharmaceutical and physical interventions to decrease fatigability and improve physical functioning.

Study objective

1) The Motor Fatigability Test is a reproducible and valid outcome measure for fatigability of the skeletal muscles in patients with SMA

2) The Respiratory Fatigability Test is a reproducible and valid outcome measure for fatigability of the respiratory muscles in patients with SMA

3) Fatigability in SMA patients is associated with neuromuscular junction dysfunction

Study design

June 2014 – November 2015: selection of subjects and obtaining informed consent

July 2014 – December 2015: testing subjects

December 2014 - December 2015: Analyses

January 2015 - June 2016: final data analysis and writing of manuscripts.

Intervention

Psychometric study on validity and reproducibility of fatigability tests

Contacts

Public
Kinderbewegingscentrum | Wilhelmina Kinderziekenhuis | Universitair Medisch Centrum Utrecht
Lundlaan 6, 3508 AB Utrecht
B. Bartels
Utrecht
The Netherlands
+31 (0)88 75 54030
Scientific
Kinderbewegingscentrum | Wilhelmina Kinderziekenhuis | Universitair Medisch Centrum Utrecht
Lundlaan 6, 3508 AB Utrecht
B. Bartels
Utrecht
The Netherlands
+31 (0)88 75 54030

Eligibility criteria

Inclusion criteria

1) Subjects with SMA

- Genetically confirmed diagnosis of SMA type 2 or type 3 or type 4

-Ability to follow test instructions

-Parental informed consent/Inform consent

-Age 8-50 years

2) Patient control group (matched on clinical status)

-Genetically confirmed diagnosis of (neuro-) muscular disease, no signs of neuromuscular dysfunction

-Ability to follow test instructions

-Parental informed consent/ Informed consent

-Age 8-50 years

3) Healthy control group (age and gender matched)

-Sufficient understanding of Dutch

-Ability to follow test instructions

-Parental informed consent/ Informed consent

-Age 8-50 years

Exclusion criteria

All subjects:

Concomitant medical problems that might intervene with the outcomes of the testing

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel

Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-06-2014
Enrollment:	150
Type:	Anticipated

Ethics review

Not applicable

Application type:	Not applicable

Study registrations

Followed up by the following (possibly more current) registration

ID: 44457
Bron: ToetsingOnline
Titel:

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

No registrations found.

In other registers

Register	ID
NTR-new	NL4436
NTR-old	NTR4558
CCMO	NL48715.041.14
OMON	NL-OMON44457

Study results