Fatigability in SMA: validity and reproducibility of tests.

Gepubliceerd: 01-04-2014 Laatst bijgewerkt: 15-05-2024

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...

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON29501

Bron
Nationaal Trial Register

Aandoening

SMA
Spinal Muscular Atrophy
Fatigability

Ondersteuning

Primaire sponsor: University Medical Center Utrecht
Overige ondersteuning: Stichting Spieren voor Spieren

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

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)

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

Psychometric study on validity and reproducibility of fatigability tests

Contactpersonen

Publiek

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

Wetenschappelijk

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

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

All subjects:

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-06-2014
Aantal proefpersonen:	150
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 44457
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten