

Critical Illness Polyneuromyopathy - The effect of electrical nerve stimulation.

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Muscle weakness in patients admitted to the Intensive Care Unit lengthens duration of mechanical ventilation, weaning and hospital stay. One of the causes for muscle weakness is critical illness polyneuromyopathy (CIPM). The incidence of CIPM varies...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON22801

Bron

NTR

Verkorte titel

CIPM08

Aandoening

Critical Illness polyneuromyopathy
ICU-acquired weakness
Critical Illness polyneuromyopathie
electrical stimulation
elektrische zenuwstimulatie

Ondersteuning

Primaire sponsor: JG Grandjean

Medisch Spectrum Twente, Thoraxcentrum
Haaksbergerstraat 55, 7513 ER Enschede
0534872000

Overige ondersteuning: JG Grandjean

Medisch Spectrum Twente, Thoraxcentrum
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Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Difference in muscle force (percentage) between stimulated and non-stimulated legs on day 1 and day 10.

Toelichting onderzoek

Achtergrond van het onderzoek

Muscle weakness in patients admitted to the Intensive Care Unit (ICU) lengthens duration of mechanical ventilation, weaning and hospital stay. One of the causes for muscle weakness is critical illness polyneuromyopathy (CIPM). The incidence of CIPM varies between 25 and 100%, depending on patient population, diagnostic criteria and timing of measurements. Despite many previous studies, the pathophysiology and risk factors of CIPM remain unclear. More importantly, there is yet no therapy for this disease. Electrical stimulation has shown to improve muscle strength, cross-sectional area of muscle and prevent muscle atrophy. We hypothesize that electrical stimulation of nerves in patients with CIPM will improve muscle strength.

Patients who are expected to be admitted to the thoracic ICU for longer than 2 days will be included in this study. Some of these patients will develop CIPM. Patients will receive muscle force measurements of the M. extensor hallucis longus on day 0. On day 1-10 muscle force and electrophysiological measurements will take place daily. On day 1-9 electrical stimulation of the N. peroneus communis on one leg will be applied for 30 minutes. Randomization determines which leg will be stimulated (dominant or non-dominant). The primary outcome measure is the difference in muscle force (percentage) between stimulated and non-stimulated legs on day 1 and day 10. Also, electrophysiological measurements will be evaluated.

Doel van het onderzoek

Muscle weakness in patients admitted to the Intensive Care Unit lengthens duration of mechanical ventilation, weaning and hospital stay. One of the causes for muscle weakness is critical illness polyneuromyopathy (CIPM). The incidence of CIPM varies between 25 and 100%, depending on patient population, diagnostic criteria and timing of measurements. Despite many previous studies, the pathophysiology and risk factors of CIPM remain unclear. More importantly, there is yet no therapy for this disease. Electrical stimulation has shown to improve muscle strength, cross-sectional area of muscle and prevent muscle atrophy. We hypothesize that electrical stimulation of nerves in patients with CIPM will improve muscle strength.

Onderzoeksopzet

Patients will receive muscle force measurements of the M. extensor hallucis longus on day 0. On day 1-10 muscle force and electrophysiological measurements will take place daily. On day 1-9 electrical stimulation of the N. peroneus communis will be applied.

Onderzoeksproduct en/of interventie

Electrical nerve stimulation of the N. peroneus communis on one leg. Randomization determines whether the dominant or non-dominant leg is stimulated. Stimulation will be applied daily for 30 minutes on 9 weekdays.

Contactpersonen

Publiek

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Age above 18 years;
2. aortic surgery;
3. mitral valve repair or replacement surgery;

4. double valve surgery;
5. coronary artery surgery with poor left ventricle function;
6. patients scheduled for cardiovascular surgery with chronic kidney failure or kidney-function disorders;
7. COPD patients scheduled for cardiovascular surgery with FEV1 < 1.5 Liter;
8. patients with preexisting pulmonary disorders scheduled for cardiovascular surgery;
9. admission at thoracic ICU;
10. obtained informed consent.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Existing neuropathy or myopathy;
2. not having 4 limbs.

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Niet-gerandomiseerd
Blinding:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland	
Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-02-2009
Aantal proefpersonen:	10
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum: 10-12-2008

Soort: Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL1508
NTR-old	NTR1578
Ander register	METC Medisch Spectrum Twente : P08-50
ISRCTN	ISRCTN wordt niet meer aangevraagd

Resultaten