Effect of early mobilisation combined with additional protein on muscle mass in critically ill patients

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We hypothesize that early mobilisation followed by additional protein intake is more effective in preservation of muscle mass than early mobilisation and optimal nutrition separately.

Ethische beoordeling	Niet van toepassing
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON20948

Bron
NTR

Verkorte titel
TRAIN-ICU

Aandoening

Decline in muscle mass during ICU admission.

Ondersteuning

Primaire sponsor: Medisch Spectrum Twente
Overige ondersteuning: None

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Muscle thickness of the mid-upper arm, forearm and thigh measured by ultrasonography

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Muscle atrophy occurs often on the Intensive Care Unit (ICU) and has a negative impact on mortality, weaning from mechanical ventilation, the amount of days at the ICU and physical functioning after hospitalisation. Both early mobilisation as well as optimal nutritional support are important to reduce the amount of muscle loss. We hypothesize that early mobilisation followed by additional protein intake is more effective in preservation of muscle mass than early mobilisation and optimal nutrition separately.

Objective: Is additional protein delivery directly after mobilization effective in delaying muscle atrophy (measured by muscle thickness determined with ultrasonography) in subjects with critical illness compared to early mobilization and continuous protein delivery only.

Study design: Randomised controlled trial, not single blinded.

Study population: All critically ill adults who were expected to stay at least 72 hours on the ICU.

Intervention (if applicable): Intervention group: Optimal feeding (proteins 1.5 g/kg), early mobilization (3 times a day), directly after mobilization additional 15 grams of proteins. Control group: Optimal feeding (proteins 1.5 g/kg) and early mobilization (3 times a day). Main study parameters/endpoints: The main study parameter is the percent change in muscle thickness of the mid-upper arm, forearm and thigh measured by ultrasonography, from baseline to ICU admission.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

The largest part of the intervention is standard care. The extra burden is a weekly ultrasonography and Biva measurement. Both are non-invasive measurements, performed at patient's bedside and ready within a few minutes. Next a 6-item questionnaire is done 3 times, these questionnaire takes 5 minutes. The additional 45 grams of protein is within the safe range of 2-2.5 g/kg (since the optimal feeding of protein is set on 1.5 g/kg).
The possible benefit is more preservation of muscle mass during ICU admission.

Doel van het onderzoek

We hypothesize that early mobilisation followed by additional protein intake is more effective in preservation of muscle mass than early mobilisation and optimal nutrition separately.

Onderzoeksopzet

Day 5, 10 and 14, at ICU discharge, at hospital discharge, and after 3 months follow-up

Onderzoeksproduct en/of interventie

Intervention group: Optimal feeding (proteins 1.5 g/kg), early mobilization (3 times a day), directly after mobilization additional 15 grams of proteins. Control group: Optimal feeding (proteins 1.5 g/kg) and early mobilization (3 times a day).

Contactpersonen

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Included and randomized in the study within 48 hours after ICU admission.

- Expected to stay on the ICU for at least 72 hours.

- Complete enteral nutrition. Or enteral nutrition in combination with parenteral or oral nutrition.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

-Complete parenteral feeding -> administration of ProSource not possible

-Chronic renal failure or hepatic encephalopathy -> absolute contraindications of supplemental protein

-Acute kidney injury without CVVH or IHD -> relative contra-indication.22

-Poor prognosis (Anticipated mortality within 72 hours)

-Progressive neuro-muscular disease or neurotrauma

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-03-2018
Aantal proefpersonen:	40
Type:	Verwachte startdatum

Ethische beoordeling

Niet van toepassing

Soort:	Niet van toepassing

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	NL6820
NTR-old	NTR7010
Ander register	NL64051.044.17 : METC Twente P18-01

Resultaten

Samenvatting resultaten
None