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

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON20948

Source
NTR

Brief title
TRAIN-ICU

Health condition

Decline in muscle mass during ICU admission.

Sponsors and support

Primary sponsor: Medisch Spectrum Twente
Source(s) of monetary or material Support: None

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

• muscle quality (echogenicity determined with ultrasonography);

• nutritional state and hydration status (Biva measurement);

• muscle force (MRC-sum and handgrip force);

• functional status (DEMMI);

• quality of life (EQ-5D);

Study description

Background summary

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.

Study objective

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.

Study design

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

Intervention

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).

Contacts

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Eligibility criteria

Inclusion criteria

- 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.

Exclusion criteria

-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

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-03-2018
Enrollment:	40
Type:	Anticipated

Ethics review

Not applicable
Application type: Not applicable

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
NTR-new	NL6820
NTR-old	NTR7010
Other	NL64051.044.17 : METC Twente P18-01

Study results

Summary results
None