THE IMPACT OF HIGH VERSUS STANDARD ENTERAL PROTEIN PROVISION ON FUNCTIONAL RECOVERY FOLLOWING INTENSIVE CARE ADMISSION: A RANDOMIZED CONTROLLED, MULTICENTER, PARALLEL GROUP TRIAL IN MECHANICALLY VENTILATED, CRITICALLY ILL PATIENTS

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To investigate whether increased protein provision in critically ill patients during Intensive Care Unit (ICU) admission can improve functional outcome and recovery following ICU discharge

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON52851

Source
ToetsingOnline

Brief title
PRotEin provision in Critical IllneSs (PRECISe)

Condition

- Other condition

Synonym
Critical illness, IC admission

Health condition

Critical illness (aandoening die IC opname nodig maakt)

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Universitair Ziekenhuis Maastricht
Source(s) of monetary or material Support: ZonMW en KCE (BeNeFIT call),Nutricia

Intervention

Keyword: Critical illness, Enteral Protein

Outcome measures

Primary outcome

Overall between group-differences in health Related Quality of Life (HRQL) at

30 days, 90 days and 180 days after index ICU admission, assessed by EuroQoL

(EQ-5D-5L).

Secondary outcome

Established Core Outcome Measures Set developed by an international expert

panel using Delphi consensus methods:

• Overall survival

• Changes in health-related quality of life, as assessed by Short Form 36

(SF-36) questionnaire, completed at 30 days, 90 days and 180 days after ICU

admission

• Changes in the mental health status, assessed by the Hospital Anxiety and

Depression Scale (HADS) EQ-VAS of the EQ-5D-5L and IES-R Impact of Event Scale,

all completed at 30 days, 90 days and 180 days after ICU admission

• Changes in the pain level, assessed by the pain question of the EQ-5D-5L

questionnaire, completed at 30 days, 90 days and 180 days after ICU admission

• Changes in physical function, as assessed by the 6-minute walk test performed

at 30 days, 90 days and 180 days after ICU admission

• Changes in muscle and nerve function, as assessed by the MRC-SUM score and

Handgrip strength (Dynamometer), performed at 30 days, 90 days and 180 days

after ICU admission

Study description

Background summary

Critical illness is characterised by a catabolic state with increased muscle protein breakdown, resulting in severe skeletal muscle wasting during ICU stay. Increased dietary protein might attenuate muscle protein catabolism and it's subsequent impact on muscle mass and function, therefore enhancing post-ICU (functional) recovery.

Study objective

To investigate whether increased protein provision in critically ill patients during Intensive Care Unit (ICU) admission can improve functional outcome and recovery following ICU discharge

Study design

The PRECISe trial is a pragmatic, international multi-center, randomized controlled, triple-blinded study in adult, mechanically ventilated patients, admitted to an Intensive Care Unit.
The study consists of 3 phases:
* Screening phase: starting from identifying a study subject until the first nutrition will be given.
* Treatment phase: starting from the first nutrition until ICU discharge or a maximum of 90 days of ICU admission.
* Follow-up phase: starting when the treatment phase ends until 180 (± 4) days

after ICU admission.

Intervention

comparing two isocaloric, isovolumetric enteral feeds with either
- a standard (5g protein/100 kcal) or
- a high (8g protein/100 kcal) protein content

Study burden and risks

For this study, mechanically ventilated patients admitted to the ICU will be studied. This is a vulnerable patient group that, due to the nature of their condition, will not able to give informed consent before start of the study. However, alternative models or patients are not able to answer our research question, as it is specific for this patient group, making it necessary to perform this study in a vulnerable population. Critical illness (for which mechanical ventilator support is necessary for an undetermined period) is a severe, life-threatening disease with unique and detrimental metabolic derangement resulting in a spectacularly rapid loss of muscle mass and strength unlike any other disease state. Therefore, previous work on the effectiveness of protein provision on function recovery in healthy or less severe disease conditions cannot simply be extrapolated to ICU patients. However, the increased protein catabolism and impaired anabolic response during ICU admission has a severe impact on the recovery and functional outcome in critically ill patients, both in the short and long-term.
The PRECISe study aims to investigate whether the enteral protein administration is able to improve functional recovery following ICU admission. If the study is able to show a benefit of one treatment arm over the other, the results will be implemented in daily practice where they will lead to better treatment of critically ill patients. Therefore, this study has the potential to improve care for this patient population and therefore outweighs the objection that it requires the study to be performed in a study population unable to give informed consent by themselves.

No additional risks are involved in the study. The study compares nutritional strategies that are currently used in daily ICU practice and both strategies have proven to be safe, well tolerated and without any additional side effects.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

* Adult (>= 18 years) patient admitted to the ICU
* Unplanned ICU admission
* Invasive mechanical ventilation initiated <24 hours following ICU admission
* Expected ICU stay on mechanical ventilation of >= 3 days

Exclusion criteria

* Contraindication for enteral nutrition at the discretion of the treating physician
* Moribund or expected withholding of treatment
* Kidney failure and *no dialysis*-code on admission
* Hepatic encephalopathy (West Haven criteria 3-4)
* Body mass index <18 kg/m²

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	19-11-2020
Enrollment:	515
Type:	Actual

Ethics review

Approved WMO Date:	05-10-2020
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	21-10-2022
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)
Approved WMO Date:	13-01-2023
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Approved WMO

Date:	12-01-2024
Application type:	Amendment
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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
ClinicalTrials.gov	NCT04633421
CCMO	NL73247.068.20