ProtEE study

Gepubliceerd: 22-05-2021 Laatst bijgewerkt: 13-12-2022

The course of resting energy expenditure (REE), measured by indirect calorimetry changes based on standard versus high enteral protein feeding in the ICU.

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

Samenvatting

ID

NL-OMON20841

Bron
NTR

Verkorte titel
ProtEE

Aandoening

Conditions required ventilator support in the Intensive Care Unit

Ondersteuning

Primaire sponsor: Maastricht UMC
Overige ondersteuning: Hospital Gelderse Vallei, Ede

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

To compare the course of resting energy expenditure (REE), measured by indirect calorimetry, during ICU stay (and after that until hospital discharge, when feasible), between patients fed with high versus standard enteral protein within the PRECISe trial.

Toelichting onderzoek

Achtergrond van het onderzoek

In this study, all patients consented into either arm of the PRECISe trial in one of the centres participating in the ProtEE substudy, will be screened for the additional ProtEE in- and exclusion criteria. Patients that meet all the inclusion criteria and none of the exclusion criteria will be included in this observational study in consecutive order. The indirect calorimeter will be used to measure REE parameters during ICU stay, within 24 hours of admission and once every third day (+/- 1 day) after that. The admission weight will be entered in all measurements to minimize the effect of fluid overload. Participating centres with access to a canopy-hood to measure REE in spontaneously breathing patients will continue measurements every 3rd day (+/- 1 day), after extubation and once a week in the ward after ICU-discharge, until hospital discharge, if feasible. All measurements will be performed in a steady-state situation (an RQ within physiologic range of 0.67 – 1.3 and a period of gas exchange defined by a 5-min interval during which VO2 and VCO2 vary by < 10%.). The output from the indirect calorimetry meter will not be used to adjust enteral nutrition dosage or composition as to not interfere with the PRECISe trial.

Doel van het onderzoek

The course of resting energy expenditure (REE), measured by indirect calorimetry changes based on standard versus high enteral protein feeding in the ICU.

Onderzoeksopzet

Measurements will be done with the Q-NRG® Metabolic Monitor. From the start of the study until hospital discharge the measurements with the Metabolic Monitor will be assessed every third day (+/- 1 day), and, if feasible, once per week (+/- 1 day) after the 2nd measurement in general wards, or on the day of hospital discharge, whichever comes first.

The measurements for the MRC sum-score as mentioned in the secondary outcome will not be measured in this study, this will be done in the PRECISe core trial.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Any patient admitted to the intensive care unit must meet all of the following criteria to be eligible for the PRECISe study:

1. Adult ≥ 18 years-old admitted to the ICU
2. Unplanned ICU admission
3. Invasive mechanical ventilation initiated <24 hours of ICU admission
4. Expected ICU stay on ventilator support of ≥ 3 days

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

Any patient admitted to the Intensive Care Unit meeting one or more of the following criteria is not eligible for the PRECISe study:

1. Contraindication for enteral nutrition
2. Moribund or expected withholding of treatment
3. Kidney failure with “no dialysis”-code on admission
4. Hepatic encephalopathy (West Haven 3 – 4)
5. Body-mass index <18 kg/m²

Additional exclusion criteria ProtEE study:
1. Fraction of inspired oxygen (FiO2) expected to remain > 0.7 for 24 hours after admission.
2. Positive end-expiratory pressure (PEEP) expected to remain > 12 cm H_2O for 24 hours after admission.
3. Patient is on ECMO the first 24h after admission

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	22-05-2021
Aantal proefpersonen:	400
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

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	NL9510
Ander register	BCWO Hospital Gelderse Vallei : BCWO 2101-014

Resultaten