Protein intake, tolerance and safety of a new high protein tube feed in critically ill overweight ICU patients as compared to standard tube feed.

Gepubliceerd: 02-02-2016 Laatst bijgewerkt: 18-08-2022

It is hypothesized that the outcome of the outcome parameters will be superior for the test product compared to the control product: No difference for the test product compared to the control product is anticipated for the outcome parameter...

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

Samenvatting

ID

NL-OMON28901

Bron
NTR

Verkorte titel
PROTILL

Aandoening

Catabolic state induced by severe diseases

Ondersteuning

Primaire sponsor: Nutricia Research B.V.
Uppsalalaan 12,
3584 CT Utrecht - The Netherlands
Overige ondersteuning: no secondary sponsor

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

protein intake (g/kg BW/day)

Toelichting onderzoek

Achtergrond van het onderzoek

pending

Doel van het onderzoek

It is hypothesized that the outcome of the outcome parameters will be superior for the test product compared to the control product:

No difference for the test product compared to the control product is anticipated for the outcome parameter Gastrointestinal tolerance and safety.

Onderzoeksopzet

Time points of the outcome; for example: V0 (screening); Day 1 – Day 28, FU call day 42.

Onderzoeksproduct en/of interventie

Duration of intervention: 28 days

Intervention group: High protein tube feed

Control group: Isocaloric control tube feed

Contactpersonen

Publiek

Gerben Hofman
PO box. 80141

Utrecht 3508CT
The Netherlands
T: +31 (0)30 2095000

Wetenschappelijk

Gerben Hofman
PO box. 80141

Utrecht 3508CT
The Netherlands
T: +31 (0)30 2095000

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- 18 years and over

- Male and female

- Patient: ICU stay and indication for tube feed via nasogastric tube

- BMI > 25.0 kg/m2

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Requiring other specific tube feed for medical reason.

- Having any contra-indication to receive tube feed such as severe shock, presence of partial or complete mechanical bowel obstruction, or intestinal ischemia or infarction.

- Abnormalities in GI tract which may impact GI function, such as short bowel syndrome - defined as entire length of small bowel totalling 122 centimetres or less-, Ulcerative Colitis or Crohn’s disease or any form of enterostomy

- GI tract, abdominal or bariatric surgery within 72 hours before start intake study product or expected in the next 5 days after start study product intake

- History of chronic pancreatitis or acute pancreatitis

- Expected to need parenteral feeding

- Expected to need protein supplementation other than study product

- SOFA score >12 from admission to the ICU until 24 hours after admission or until randomisation in case of randomisation before 24 hours after admission

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Dubbelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	15-02-2016
Aantal proefpersonen:	44
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	02-02-2016
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	NL5536
NTR-old	NTR5654
Ander register	: NTS.2.C/A

Resultaten

Samenvatting resultaten
pending