Gastrointestinal tolerance of an upgraded peptide feed in ICU patients

No registrations found.

Ethical review	Positive opinion
Status	Recruiting
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28333

Source
NTR

Brief title
STEPP

Health condition

Gastrointestinal tolerance in ICU patients

Sponsors and support

Primary sponsor: Nutricia Research B.V.
Uppsalalaan 12,
3584 CT Utrecht - The Netherlands
Source(s) of monetary or material Support: not applicable

Intervention

Outcome measures

Primary outcome

Gastrointestinal tolerance

Secondary outcome

Clinical outcomes: ICU stay, hospital stay, ventilator free days, mortality, SOFA (sub)score(s)

Safety: (S)AE’s and laboratory blood parameters

Study description

Background summary

pending

Study design

Screening

Intervention: Day 1 – Day 14

Follow-up: Day 28

Intervention

Duration of intervention: 14 days

Intervention group: Peptide based tube feed

Control group: Isocaloric commercially available tube feed

Contacts

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Eligibility criteria

Inclusion criteria

Main inclusion criteria:

• Age >=18 years;

• Admitted to the ICU;

• Expected to be on tube feeding for >=5 days;

• Start of tube feeding within 48 hours after ICU admission

Exclusion criteria

Main exclusion criteria:

• Requiring other tube feed for medical reason;

• Not suitable for tube feeding;

• Allergy or intolerance for cow’s milk protein, soy or pea protein;

• Gastrointestinal disease such as Crohn’s or Ulcerative Colitis or other conditions affecting absorption such as short bowel syndrome;

• Pancreatic, liver or renal failure;

• Sequential organ failure assessment (SOFA) score >12 within first 24 hours after admission;

• Being pregnant;

• Participating in another clinical intervention trial

Study design

Design

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	24-10-2016
Enrollment:	30
Type:	Anticipated

Ethics review

Positive opinion

Date:	14-10-2016
Application type:	First submission

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	NL5798

Register ID

NTR-old	NTR6073
Other	REC Reference number: 16/LO/1486 : Protocol number: MPR16TA06066

Study results

Summary results
pending