GI tolerance study in critically ill model (CIM)

No registrations found.

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

Summary

ID

NL-OMON27330

Source
NTR

Brief title
CIM study

Health condition

Gastrointestinal tolerance in healthy volunteers in which gastric conditions of critically ill patients will be mimicked by medication.

Sponsors and support

Primary sponsor: Nutricia Research B.V.
Uppsalalaan 12,
3508 CT Utrecht – the Netherlands
Source(s) of monetary or material Support: Not applicable

Intervention

Outcome measures

Primary outcome

Gastric content volume

Secondary outcome

Plasma amino acid concentrations

Study description

Background summary

This study will investigate the effect of composition of enteral feeding on gastric content volume during continuous feeding. The study will be a randomized, controlled, open label, cross-over, single centre study. The study will be performed in healthy volunteers in which gastric conditions of critically ill patients will be mimicked by medication. Subjects will be continuously fed for 4-hours with the intervention product (whey dominant tube feed) or control product (casein dominant tube feed). Before, during and after feeding the gastric content volume will be studied.

Study objective

It is hypothesized that the outcome of the primary outcome parameter will be different for the test product compared to the control product.

Study design

V0 (screening day -21 until day -4); V1 (day 1); V2 (day 15)

Intervention

Duration of intervention: 4 hours

Intervention product: whey dominant tube feed

Control product: casein dominant tube feed

Contacts

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Eligibility criteria

Inclusion criteria

Main inclusion criteria

1. Age between 18 and 50 (including 18 and 50) years

2. Being in good health as to the judgement of the investigator

3. Written informed consent

Exclusion criteria

Main exclusion criteria

1. Known history of any disorders such as; gastrointestinal (GI), cardiovascular, respiratory, hematological, renal, hepatic, hypothyroidism, psychiatric panic attacks and/or diabetes mellitus and/or a history of brain tumor, an enlarged prostate or urination problems and/or recent head injury

2. Presence of implants, devices, or metallic foreign bodies interacting with MRI

3. A low systolic blood pressure (<100 mm Hg) in supine position

4. Pregnancy or breastfeeding

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	31-03-2017
Enrollment:	20
Type:	Anticipated

Ethics review

Positive opinion

Date:	17-05-2017
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	NL6243

Register	ID
NTR-old	NTR6423
Other	Commissie Medische Ethiek UZ KU Leuven : S59976

Study results

Summary results
Pending