Discriminatory values of the citrulline generation test (CGT) following enteral and intravenous administration of glutamine-alanine in stable ICU patients.

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Primary aim1. To determine discriminatory CGT values in *stable* ICU patients who are able to tolerate enteral nutrition meeting their full protein-energy requirementsSecondary aims2. To determine the effects of enteral and intravenous glutamine...

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON31306

Source
ToetsingOnline

Brief title
The GLUTSTIM study

Condition

- Other condition

Synonym
malabsorption, small bowel (enterocyte) function

Health condition

stabiele intensive care patienten met allerlei onderliggende aandoeningen

Research involving

Human

Sponsors and support

Primary sponsor: Vrije Universiteit Medisch Centrum
Source(s) of monetary or material Support: Stichting Velpeau-onderzoeksstichting van de IC

Intervention

Keyword: citrulline, enterocyte function, glutamine, malabsorption

Outcome measures

Primary outcome

The determination of discriminatory CGT values in *stable* ICU patients who

are able to tolerate enteral nutrition meeting their full protein-energy

requirements

enteral enery losses (using bomb calorimetry)

Secondary outcome

The determination of the effects of enteral and intravenous glutamine

administration on CGT values in these patients.

The assessment of differences in plasma citrulline concentrations following

venous and arterial blood sampling, respectively

Study description

Background summary

At present there is no feasible test available for the assement of enterocyte function as a measure of the absorptive capacity of the small bowel. In patients with known enterocyte dysfunction (IBD, coeliac disease) stimulation of the enterocytes by a glutamine load (The Citrulline Generation Test) a socalled subnormal resposne has been demonstrated by our group. One could specualte on the frequent occurrence of intstinal failure in critically ill patienst mainly due to ischemia of the digestive tract.
In this study proposal we aim to assess discriminatory values for the *citrulline generation test* (CGT) in 12 *stable* ICU patients on full enteral nutrition without any known small intestinal disorders. Additional aims are to determine differences in CGT curves obtained following enteral and intravenous administration of alanine-glutamine and to assess differences in plasma citrulline concentrations following venous and arterial blood sampling, respectively.

Study objective

Primary aim
1. To determine discriminatory CGT values in *stable* ICU patients who are able to tolerate enteral nutrition meeting their full protein-energy requirements

Secondary aims
2. To determine the effects of enteral and intravenous glutamine administration on CGT values in these patients.
3. To assess differences in plasma citrulline concentrations following venous and arterial blood sampling, respectively.

Study design

prospective cohort study

Intervention

The citrulline generation test.

Study burden and risks

Dipeptiven administration is part of our routine nutritional therapy, mainly as an adjunctive to TPN. No clear side effcts are known.

Sampling is performed from existing blood lines, without the need for extra punctures. The total amount of blood collection is 72 ml.

For the 2 CGTs the patient needs to fast for at least 6 hrs. The enteral nutrition will therefor be withdrawn, while we wil closely watch glucose levels.

Feces collection is routine on the ICU using special collection bags. No disconfort will be noted by the patient.

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

1. age between 18-80
2. informed consent
3. fecal production< 250 gr/24 hrs
4. stable ICU patient
5. full enteral nutrition

Exclusion criteria

no signs of malabsorption, liver cirrhosis, steroids (> 10 mg/dag), pregnancy, partenteral nutrition

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-12-2007
Enrollment:	12
Type:	Actual

Ethics review

Approved WMO Date:	17-12-2007
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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
CCMO	NL18743.000.07