The contribution of L-glutamine to L-citrulline and L-arginine synthesis, when L-alanyl-L-glutamine is supplied in an enteral or parenteral dose of 0,5 g/kg/day, in surgical patients

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The main objective of this clinical study is to investigate the effect of the administration of glutamine, provided as alanyl-glutamine, supplemented enterally or parenterally, on the synthesis of citrulline from glutamine and the subsequent...

Ethical review	Approved WMO
Status	Will not start
Health condition type	Hepatobiliary therapeutic procedures
Study type	Interventional

Summary

ID

NL-OMON33726

Source
ToetsingOnline

Brief title
Dipetide study 0,5 g/kg/day, surgical patients

Condition

- Hepatobiliary therapeutic procedures

Synonym
upper abdominal surgery

Research involving
Human

Sponsors and support

Primary sponsor: heelkunde
Source(s) of monetary or material Support: Ministerie van OC&W,NWO 920-03185,WBSO;particuliere giften;Fresenius Kabi

Intervention

Keyword: alanyl-glutamine, metabolism, supplementation, surgery

Outcome measures

Primary outcome

The effect of the supplementation of glutamine on the metabolism of glutamine,

citrulline and arginine, as well as the conversions of glutamine into

citrulline and citrulline into arginine at organ and whole body level in

surgical patients.

Secondary outcome

Rate of appearance of phenylalanine (Phe) and the conversion of Phe into

tyrosine (Tyr) will be used to calculate protein breakdown and synthesis.

Study description

Background summary

Numerous clinical studies have demonstrated that glutamine supplemention of 12-30 g/day results ina favorable outcome as reflected by a reduced length of hospital stay, a reduction in mortility in intensive care patients, a reduction in infectious morbidity in severe trauma patients, a reduction in post-ICU interventions and a significant reduction in hospital costs.
However, the underlying mechanisms are not fully clear.
The positive effect of glutamine could partly be due to the substrate that glutamine delivers for citrulline and subsequent arginine synthesis. Arginine is important for wound healing, preservation of the immune system and it serves as a nitrogen donor for nitric oxide. Nitric oxide can regulate flow towards and through vital organs.
During trauma and sepsis, plasma concentrations of arginine are decreased due

to an increased requirement under these conditions of arginine for the synthesis of NO, acute phase proteins and proteins in general.
In our previous studies, the importance of the contribution of glutamine for citrulline and arginine synthesis was demonstrated. The route of administration as well as the influence of the structure of glutamine (as a mono- or a dipeptide) was studied.
As a result metabolism on organ and whole body level is now unraveled and it appears that the gut metabolizes glutamine in a different way when glutamine is supplied via different routes.

However, the effect of a relevant clinical dosage of glutamine (30 g; or 45 g as a dipeptide) supplementation on organ and whole body level remain unclear.

Study objective

The main objective of this clinical study is to investigate the effect of the administration of glutamine, provided as alanyl-glutamine, supplemented enterally or parenterally, on the synthesis of citrulline from glutamine and the subsequent synthesis of arginine from citrulline.

Study design

The proposed study is an open, exploratory clinical study of balanced (sex and age distribution), groups of surgical patients.

Intervention

Group A (case: n=6): from the day before surgery and start tracer protocol until closure of the tracer protocol: 0.042g/kg/h alanyl-glutamine IV.
Group B (case: n=6): from the day before surgery and start tracer protocol until closure of the tracer protocol: 0.042g/kg/h alanyl-glutamine ENT. The day before surgery alanyl-glutamine will be provided as a drink. During surgery alanyl-glutamine will be supplied through a naso-duodenal tube, which will be placed shortly after induction of anesthesia.
Group C (control: n=4): only tracers of glutamine, citrulline and arginine IV
Of all patients (n=16), we will study metabolism at whole body level and metabolism of the portally drained viscera, the liver and kidneys.

Study burden and risks

Participation will be under anesthesia, and will therefore not be experienced as a burden. Potential risk factors will be placement of the nasoduodenal tube (by surgeon) and blooddrawing.

Contacts

Public
Selecteer

postbus 5800
6200AZ Maastricht
Nederland
Scientific
Selecteer

postbus 5800
6200AZ Maastricht
Nederland

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Scheduled for upper gastrointestinal surgery (>2h surgery)
Age between 35 and 70 y
BMI < 35
Obtained his/her informed consent

Exclusion criteria

Liver failure
Kidney failure
Pregnancy
Corticosteroids intake < 4 weeks

Insulin Dependent Diabetes Mellitus
Celiac disease, chron's disease, or other major intestinal malabsorption disorder

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	16
Type:	Anticipated

Ethics review

Approved WMO

Date:	02-11-2009
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

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	NL19544.068.08