The Impact of glutamine suppletion on outcome in patients undergoing high-risk cardiothoracic surgery.

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

Summary

ID

NL-OMON29879

Source
ToetsingOnline

Brief title
not applicable

Condition

- Heart failures
- Hepatobiliary neoplasms malignant and unspecified
- Cardiac therapeutic procedures

Synonym
heart-failure

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum

Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: cardiothoracic surgery, glutamine, heart Failure, ICU

Outcome measures

Primary outcome

Primary Outcome

* Infectious complications in the ICU and in the hospital

Secondary outcome

Secondary Outcomes

* Cardiac morbidity in the ICU and in the hospital

* Pulmonary morbidity in the ICU and in the hospital

* Gastro-intestinal morbidity in the ICU and the hospital.

* ICU mortality

* In-hospital mortality

* Length of ICU stay

* Length of hospital stay

* Impact on immune function

Study description

Background summary

The amino acid glutamine is an important substrate for numerous metabolic and immunological processes. Glutamine is the major nitrogen transporter in the

body, a significant substrate for the intestinal tract in humans, and is essential for the normal function and replication of the cells of the immune system shown both in vitro and in vivo. Glutamine is synthesized in the body in large quantities and therefore considered nonessential. It is the most abundant amino acid in the body constituting 60% of the total amino acid and amino nitrogen pool.
Reduction in free glutamine concentration in plasma is seen in response to a variety of insults such as trauma, major surgery, infection, acidosis and fasting. Postoperatively patients in a critical state develop glutamine deficiency, associated with loss of intestinal integrity and immunological and anti-oxidant response. Lowered levels of plasma glutamine have been associated with higher mortality in critical ill patients. The role of glutamine in restoring reduced glutathione levels and as a fuel for preservation of tissue metabolism implies that a reduction in the free plasma concentration of glutamine is associated with cardiac dysfunction inflicted by I/R (Ischemia/Reperfusion) injury. Studies have shown that infusions with end products of glutamine improve heart function in patients with heart failure after cardiac surgery. Also several studies have demonstrated that supplemental parenteral glutamine administration improves postoperative nitrogen balance, supports immune function, enhances the rate of protein synthesis, maintains normal gastrointestinal permeability characteristics and is associated with reduced hospitalization and mortality.

Study objective

Aim of the study is to assess the effects of supplemental parenteral L-alanyl-L-glutamine treatment on infectious, cardiac, cerebral, pulmonary and gastro-intestinal morbidity during the ICU- (Intensive Care Unit) and hospital stay in patients after high-risk cardiothoracic surgery. Furthermore, the effect on length of stay in the ICU-, hospital- and on in-hospital mortality will be studied.

Study design

This is a prospective, single center, double blind, placebo controlled randomized trial in the LUMC (Leiden University Medical Center) in Leiden, the Netherlands. A total of 80 patients, 40 in each arm, undergoing high-risk cardiothoracic surgery will receive a daily support of glutamine or placebo,

starting 1 day preoperatively and lasting for 5 postoperative days.

Intervention

Patients will be randomized to receive either placebo- or L-alanyl-L-glutamine-treatment. Treatment will start one day before surgery and continue five days thereafter. Vital characteristics will be recorded. Blood samples will be collected according to the schedule provided on page 13 of the research protocol.

Study burden and risks

Burden:
- Infusion of study-medication will take place during several daytime hours in patients already treated intra-venously.
- Bloodsampling: an additional 46 ml will be collected during 72 hours, using present arterial or venous cannulas.

Risks:
- There are no known negative effects of additional parenteral glutamine suppletion. A saline solution will be used as placebo.
- Thromboflebitis is a possible risk of venous cannulation and parenteral treatment.

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

Patients with a left ventricular ejection fraction <35%;Patients screened by the Mission! Heart Failure Program and scheduled for one of the surgical interventions in this program.

Exclusion criteria

Emergency operations
Renal impairment (creatinine clearance <25 mL/min)
Pregnancy
<18 Years old

Study design

Design

Study phase:	4
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Double blinded (masking used)
Control:	Placebo
Primary purpose:	Prevention

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	15-10-2008
Enrollment:	80
Type:	Actual

Medical products/devices used

Product type:	Medicine
Brand name:	Dipeptiven
Generic name:	L-alanyl-L-glutamine
Registration:	Yes - NL outside intended use

Ethics review

Approved WMO Date:	14-08-2006
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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
EudraCT	EUCTR2006-004217-18-NL
CCMO	NL13391.058.06