Glutamine supplementation guided by plasma glutamine levels

Published: 14-12-2017
Last updated: 16-04-2024

We want to study the effect of glutamine on duration of mechanical ventilation and lenght of stay in ICU or hospital.With the availability of a Point of Care (POCT) measurement of plasma glutamine level a measurement can be performed short after the...

Ethical review	Not approved
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON42972

Source
ToetsingOnline

Brief title
Glutamine supplementation guided by plasma glutamine levels

Condition

- Other condition

Synonym
glutamine

Health condition

voeding supplementen

Research involving
Human

Sponsors and support

Primary sponsor: Medisch Centrum Leeuwarden
Source(s) of monetary or material Support: Stichting Intensive Care Onderzoek Friesland

Intervention

Keyword: glutamine

Outcome measures

Primary outcome

Is there a difference in length of mechanical ventilation, length of stay ICU

or length of stay hospital between patients who received enteral glutamine or

not?

Secondary outcome

What is the amount of enteral glutamine supplementation needed to increase the

plasma glutamine level to a level above 420 µmol/l.Is there a difference

between hospital mortality or 6 month mortality between patients who received

enteral glutamine or not?

Is there a relationship between nutritional status (measured with

bio-impedance vector analysis) and plasma glutamine level?

Is there a relationship between the amount of supplied nutrition and the course

of plasma glutamine levels?

Is there a difference between patients admitted with sepsis or trauma compared

to other causes of admission?

Study description

Background summary

Earlier studies showed a benefit in survival when glutamine was given intravenously and these studies lead to recommendations that glutamine should be given to critically ill patients [4]. The ESPEN guidelines recommend 0,2-0,4 g/kg/d intravenous glutamine added to standard parenteral nutrition [9]. Two, recently published, large randomized controlled studies in critically ill patients did not show a benefit in survival during supplementation with enteral and intravenous glutamine [6,7]. The outcome of these trials have led to a discussion whether it is appropriate to give glutamine supplementation. Several explanations can be given for these differences in results of the earlier studies and the two recent trials. It could well be the result of patient selection; in the Redoxs trial only patients with multiple organ failure were included whereas these patients were excluded in the earlier trials [7]. Post-hoc analysis of this trial revealed a higher percentage of patients with acute kidney injury (AKI) who received glutamine supplementation, this could have influenced outcome as AKI is a strong independent predictor of mortality during ICU admission [8]. Furthermore, in the Redoxs trial patients received higher doses of both intravenous and enteral glutamine (0,35 g/kg/d i.v. + 30 gram enteral) compared to earlier trials [7]. In the SIGNET trial a total of 20 grams of glutamine was added to parental nutrition; in this trial 47 % of patients were treated less then 5 days and the amount of parental nutrition is unclear so the dose of glutamine that patients received was less then 20 grams per day for most patients [6].
In most clinical trials, glutamine was supplemented without knowledge of the plasma glutamine levels. It is known that not all patients admitted to the ICU have a low plasma glutamine level, some patients even show a markedly increased glutamine level [10]. Previous studies showed a low plasma glutamine level in 31 to 65% of patients at the time of admission on the ICU [2-4].

Study objective

We want to study the effect of glutamine on duration of mechanical ventilation and lenght of stay in ICU or hospital.
With the availability of a Point of Care (POCT) measurement of plasma glutamine level a measurement can be performed short after the collection of blood. This offers the possibility to identify a patient with a low plasma glutamine level shortly after admission and use repeated measurements for evaluation of the response to supplementation of glutamine.

Study design

randomized controlled intervention study

Intervention

After informed consent is obtained patients are randomised to receive enteral glutamine or not (the control group). Enteral glutamine supplementation is started (day 1) at a dose of 3 sachets per day given at 6.00, 14.00 and 22.00 hr. A sachet contains 9 grams of glutamine (Glutaperos®, GLNP Life Sciences).

Study burden and risks

no risks

Contacts

Public
Medisch Centrum Leeuwarden

Henri Dunantweg 2
Leeuwarden 8901 BR
NL
Scientific
Medisch Centrum Leeuwarden

Henri Dunantweg 2
Leeuwarden 8901 BR
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

All patients admitted to the ICU with an expected stay of 48 hours or longer

Exclusion criteria

age under 18 years, readmission to the ICU, contra-indication for enteral nutrition and the use of Total Parental Nutrition

Study design

Design

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

Primary purpose: Other

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	80
Type:	Anticipated

Ethics review

Not approved

Date:	14-12-2017
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

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	NL57347.099.16