ISRCTN60549685 https://doi.org/10.1186/ISRCTN60549685

Intravenous glutamine-dipeptide and early nasojejunal feeding in severe acute pancreatitis

Submission date
01/08/2012

Recruitment status
No longer recruiting

Registration date
27/09/2012

Overall study status
Completed

Last Edited
27/11/2015

Condition category
Digestive System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
We are carrying out a study on patients with severe acute pancreatitis, which is a life-threatening disease where the pancreas becomes inflamed. Parenteral nutrition, also known as intravenous feeding, is a method of getting nutrients into the body through the veins. Other studies have shown the benefits of intravenous glutamine with total parenteral nutrition in severe acute pancreatitis. The aim of this study is to determine the effects of intravenous glutamine in severe acute pancreatitis patients who are being fed through a nasojejunal feeding tube (a tube which goes from the nose to the small intestine).

Who can participate?
Patients aged over 18 with severe acute pancreatitis.

What does the study involve?
Participants are randomly allocated into two groups. In the glutamine group, participants receive a glutamine drip for 7 days. In the control group, participants get a drip of other amino acids of the same quantity for the same period. Both groups are otherwise treated in the same way, including early nasojejunal feeding. During their hospital stay, we record the frequency of infectious complications, organ failures, the rate of operations and radiological interventions, length of hospital stay and death rate.

What are the possible benefits and risks of participating?
Glutamine drips are frequently used in intensive care, but are not so widespread in surgery, probably because other combined amino acid solutions are well-known and cheaper. It has no side effects as it is an amino acid normally found in the human body.

Where is the study run from?
Petz Aladar County Teaching Hospital, Győr, Hungary.

When is the study starting and how long is it expected to run for?
September 2008 to September 2012.

Who is funding the study?
Mulartz Henrik Surgical Foundation (Hungary).

Who is the main contact?
Nora Hajdu
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
G-2008/12

Study information

Scientific Title
A combination of intravenous glutamine-dipeptide and early nasojejunal nutrition in severe acute pancreatitis: a prospective randomized double-blind clinical trial

Study objectives
Intravenous glutamine may be beneficial with early nasojejunal feeding in prevention of septic complications in severe acute pancreatitis.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Regional Science and Research Ethics Commitee of Petz Aladar Teaching Hospital, 04/09/2008, ref: 76-1-28/2008

Study design
Single-center prospective randomized double-blind clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details below to request a patient information sheet

Health condition(s) or problem(s) studied
Severe acute pancreatitis

Interventions
The trial will involve about 60patients, admitted to the surgical department of Petz Aladar County Teaching Hospital, Gyor, Hungary. Participants will recieve the same treatment according to local guidelines, including early nasojejunal nutrition and radiological and surgical interventions, if neccessary, exept for the supplementation of amino acids. Glutamine group will get glutamine, while control group will get a combination of other amino acids usually used in clinical practice as an intravenous supplementation. Participation will start on admission and end at dismissal from hospital.

Intervention Type
Supplement

Primary outcome measure
1. Rate of pancreas-specific infectious complications
2. Organ failures

Secondary outcome measures
1. Comparison of radiological and surgical interventions
2. Length of hospital stay
3. Mortality rate

Overall study start date
04/09/2008

Completion date

04/09/2012

Eligibility

Key inclusion criteria
1. Patients admitted with severe acute pancreatitis
2. Glasgow score at least 3 or CRP level over 150 mg/ml

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
30 patients in each groups

Key exclusion criteria
1. Age under 18 years
2. Pregnancy
3. Patients with complaints starting before the last 48 hours of admission
4. Death within 48 hours of admission

Date of first enrolment
04/09/2008

Date of final enrolment
04/09/2012

Locations

Countries of recruitment
Hungary

Study participating centre
The Mulartz Henrik Surgical Foundation
Gyor
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Sponsor information

Organisation
The Mulartz Henrik Surgical Foundation (Hungary)

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Sponsor type
Research organisation

Funder(s)

Funder type
Research organisation

Funder Name
The Mulartz Henrik Surgical Foundation (Hungary)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration