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Importance of glutamine supplementation in critical patients

Submission date	Recruitment status
26/09/2013	No longer recruiting
Registration date	**Overall study status**
08/10/2013	Completed
Last Edited	**Condition category**
24/02/2016	Nutritional, Metabolic, Endocrine

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Rapid onset of resistance to insulin is an important part of stress metabolism in major trauma patients. Recent studies confirm the role of amino acids (especially glutamine) in glucose transportation and the benefits of amino acid supplementation . The purpose of this study is to find out about the incidence of high blood glucose, the need for insulin therapy and the average daily requirement of insulin in critical trauma patients with amino acid (Dipeptiven) supplementation versus standard nutritional support.

Who can participate?
Adult multiple trauma patients can participate in the study.

What does the study involve?
Patients are randomly divided into two groups. Patients in the first group received amino acid supplementation, while patients in the second group received standard nutritional support.

What are the possible benefits and risks of participating?
The benefits for patients are better control of glucose level and less need for insulin, meaning a lower risk of low blood glucose. There are no studies or reports on possible side effects of amino acid supplementation in critical patients.

Where is the study run from?
The study included patients admitted in the intensive care unit (ICU) of the Emergency Clinical Hospital Bucharest, Romania.

When is the study starting and how long is it expected to run for?
The study started in January 2010 and ran for a period of one year.

Who is funding the study?
This is an investigator initiated and funded study (Romania).

Who is the main contact?
Dr Irina Luca Vasiliu
irinaluc@yahoo.com

Contact information

Type(s)
Scientific

Contact name
Prof Ioana Marina Grintescu

Contact details
Calea Floreasca, Nr. 4-8
Bucharest
Romania
011123
-
ioana.grintescu@rospen.ro

Additional identifiers

Study information

Scientific Title
Importance of glutamine supplementation in critical patients: a randomised controlled study

Study objectives
The purpose of this study is to evaluate the incidence of hyperglycemic episodes, the need for insulin therapy and the mean daily requirement of insulin in critical polytraumatised patients with parenteral glutamine dipeptides (Dipeptiven) supplementation versus standard nutritional support.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Emergency Clinical Hospital Bucharest; Date: 02/10/2013

Study design
Randomised controlled open-label study

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Parenteral glutamine dipeptides supplementation, hyperglycemic episodes, multiple trauma

Interventions
82 multiple trauma patients were randomised to two groups of 41, independent of sex, age (20-60 years old), injury severity score (25-50).
Group 1: Patients received parenteral supplementation with glutamine dipeptides 0.5 g/kg/day
Group 2: Patients received an isocaloric, isoproteic and isoglucidic nutritional support
The supplementation of glutamine began simultaneously with nutritional support and continued for at least 7 days. None of the patients started oral feeding in this period, the nutritional support was mainly parenteral with the least minimal enteral feeding. During the 6-day period we determined glycaemia every 6 hours, targeting to maintain values between 140 and 180 mg /dl.

Intervention Type
Supplement

Primary outcome(s)
1. Plasmatic glycemia every 4-6 hours for a 6-day period using descriptive statistics
2. Daily insulin requirements using the same method above

Key secondary outcome(s))
Amount of exogenous insulin administered in this 6-day period by ANOVA analysis

Completion date
01/01/2011

Eligibility

Key inclusion criteria
1. Young patients (over 18 years)
2. With multiple traumatic lesions
3. With an ISS over 22
4. Without significant comorbidities
5. Subjects admitted to the intensive care unit (ICU) for one year

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. BMI >30 kg/m^2
2. Renal or hepatic dysfunction
3. Diabetes mellitus
4. Reduced prior nutritional intake
5. Oral intake in the first 7 days

Date of first enrolment
01/01/2010

Date of final enrolment
01/01/2011

Locations

Countries of recruitment
Romania

Study participating centre
Calea Floreasca, Nr. 4-8
Bucharest
Romania
011123

Sponsor information

Organisation
Clinical Emergency Hospital Bucharest (Romania)

ROR
https://ror.org/03grprm46

Funder(s)

Funder type
Other

Funder Name
Investigator initated and funded (Romania)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/06/2015		Yes	No