

Importance of glutamine supplementation in critical patients

Submission date 26/09/2013	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 08/10/2013	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 24/02/2016	Condition category Nutritional, Metabolic, Endocrine	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

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Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number

N/A

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/m²
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 initiated 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