

# Importance of glutamine supplementation in critical patients

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 08/10/2013	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 24/02/2016	<b>Condition category</b> Nutritional, Metabolic, Endocrine	<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

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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

### **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**

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 measure**

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

### **Secondary outcome measures**

Amount of exogenous insulin administered in this 6-day period by ANOVA analysis

### **Overall study start date**

01/01/2010

### **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

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

We aimed to include 100 young patients (over 18 years)

**Key exclusion criteria**

1. BMI >30 kg/m<sup>2</sup>
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)

**Sponsor details**

c/o Dr. Irina Luca Vasiliu  
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Bucharest  
Romania  
020904

**Sponsor type**

Hospital/treatment centre

**ROR**

<https://ror.org/03grprm46>

**Funder(s)****Funder type**

Other

**Funder Name**

Investigator initiated and funded (Romania)

**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

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/06/2015		Yes	No