

# Inflammatory and nutritional changes during critical illness

<b>Submission date</b> 25/07/2012	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 30/07/2012	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 15/11/2019	<b>Condition category</b> Other	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Critically ill patients typically lose a lot of muscle mass despite what we feed them. Minimising muscle loss during critical illness is crucial to improving short and long term physical function after critical illness and to provide an earlier independence for this vulnerable patient group. The aim of this study is to try and determine when is the best time to feed critically ill patients so that we can try and minimise their muscle loss. We will also find out whether an amino acid supplement is useful to minimise muscle loss.

### Who can participate?

Trauma patients (head and multiple trauma) over 18 years of age admitted to the Intensive Care Unit (ICU) or High Dependency Unit (HDU) and mechanically ventilated for over 48 hours.

### What does the study involve?

Participants are randomly allocated to one of two groups. One group receives usual care - standard enteral feeding (tube feeding) given according to need. The other group receives an essential amino acid supplement given twice daily in addition to standard enteral feeding. Changes in muscle mass are measured with ultrasound so that we can see if muscle is being broken down or built up. Blood samples are collected to check for inflammation and urine samples are collected to check for muscle breakdown. The number of calories that the patients burn is measured by monitoring what the patients breathe in and out. Patients' mobility and independent function are assessed with two questionnaires.

### What are the possible benefits and risks of participating?

The results of this study will benefit critically ill patients in future by finding the best time to feed them. If essential amino acid supplementation minimises muscle mass loss, patients will benefit from earlier rehabilitation and independence. Blood, urine and breath samples are taken with routine samples to reduce patient discomfort. The essential amino acid supplement is a licensed nutritional supplement. The muscle ultrasound is a non-invasive technique.

### Where is the study run from?

Charing Cross Hospital (UK)

When is the study starting and how long is it expected to run for?  
September 2010 to March 2013

Who is funding the study?  
National Institute for Health Research (NIHR) (UK)

Who is the main contact?  
Miss Liesl Wandrag

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Miss Liesl Wandrag

**Contact details**  
Imperial College Healthcare NHS Trust  
Charing Cross Hospital  
Nutrition and Dietetic Department  
Lab block 13th floor  
Fulham Palace Road  
London  
United Kingdom  
W6 8RF

## Additional identifiers

**Protocol serial number**  
8846

## Study information

**Scientific Title**  
An investigation into inflammatory and nutritional markers during critical illness to identify an indicator of anabolism and to explore a method of attenuating muscle mass loss

**Study objectives**  
The purpose of this study is to try and determine when is the best time to feed critically ill patients so that we can try and minimise their muscle loss. We need to identify when patients build muscle rather than break muscle down and when they are best able to utilise nutrition. This will be achieved by examining both inflammatory and nutritional markers in part 1 of this study. In part 2 we will see if an amino acid supplement is useful to minimise muscle loss.

**Ethics approval required**  
Old ethics approval format

**Ethics approval(s)**  
North West London Research Ethics Committee, 26/05/2010, ref: 10/H0722/40

## Study design

Randomised interventional and observational cohort study

## Primary study design

Interventional

## Study type(s)

Treatment

## Health condition(s) or problem(s) studied

Critical care

## Interventions

Intervention group: Essential Amino Acid supplementation given twice daily in addition to standard enteral feed.

Control group: Usual care - Standard enteral feed given according to need.

## Intervention Type

Supplement

## Primary outcome(s)

Muscle change with a muscle ultrasound technique measured daily for 1st week, twice weekly after

## Key secondary outcome(s)

Functional outcomes:

1. Katz & Barthel indexes measured at day 1, 7, 14, 20
2. Indirect calorimetry measured at day 1, 5, 7, 14
3. Inflammatory markers: CRP, Albumin, cytokines measured at day 1, 5, 7, 14
4. Plasma amino acids measured at day 1, 10
5. Protein turnover with stable isotopes measured at day 1, 10, 20
6. Urinary amino acids measured at day 1, 5, 7, 14

## Completion date

01/03/2013

## Eligibility

### Key inclusion criteria

Part 1:

Intensive Care Unit (ICU):

Patients mechanically ventilated for > 48h

High Dependency Unit (HDU):

1. Trauma patients > 18 years.
2. Patients should be entered into the trial within 72h of ICU admission.

Part 2:

1. Trauma patients (head and multiple trauma) admitted to Intensive Care expected to be

ventilated for > 48h

2. Over 18 years of age

3. Patients should be entered into the trial within 72 hours of ICU admission

4. Male and female participants

5. Between 18 - 95 years

### **Participant type(s)**

Patient

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Lower age limit**

18 years

### **Sex**

All

### **Key exclusion criteria**

Part 1:

Patients expected to be ventilated for < 48h; Non-trauma HDU patients.

Part 2:

1. Medical ICU patients

2. Surgical (non-trauma) ICU patients

3. Patients enrolled in another interventional clinical trial

4. Patients where enteral feeding is contraindicated

5. Cardiac failure

6. End Stage Renal Failure

7. Chronic Obstructive Pulmonary Disease

8. Chronic liver disease (cirrhosis)

### **Date of first enrolment**

30/09/2010

### **Date of final enrolment**

01/03/2013

## **Locations**

### **Countries of recruitment**

United Kingdom

England

### **Study participating centre**

**Charing Cross Hospital**  
London  
United Kingdom  
W6 8RF

## **Sponsor information**

### **Organisation**

Imperial College London (UK)

### **ROR**

<https://ror.org/041kmwe10>

## **Funder(s)**

### **Funder type**

Government

### **Funder Name**

National Institute for Health Research (UK)

### **Alternative Name(s)**

National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

### **Funding Body Type**

Government organisation

### **Funding Body Subtype**

National government

### **Location**

United Kingdom

## **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?
<a href="#">Results article</a>	feasibility study results in ICU patients	11/09/2019	13/09/2019	Yes	No
<a href="#">Results article</a>	results in ICU patients	14/11/2019	15/11/2019	Yes	No