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Inflammatory and nutritional changes during critical illness

Submission date
25/07/2012

Recruitment status
No longer recruiting

Registration date
30/07/2012

Overall study status
Completed

Last Edited
15/11/2019

Condition category
Other

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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 to request a patient information sheet

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

Secondary outcome measures
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

Overall study start date

30/09/2010

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
UK Sample Size: 120; Description: Part 1: Observational study: 80 ICU subjects, 15 HDU subjects. Part 2: Interventional pilot study: 40 subjects (20 in each group).

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
England

United Kingdom

Study participating centre
Charing Cross Hospital
London
United Kingdom
W6 8RF

Sponsor information

Organisation
Imperial College London (UK)

Sponsor details
School of Medicine
Hammersmith Hospital
Du Cane Road
London
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United Kingdom
W12 0HS

Sponsor type
University/education

Website
http://www3.imperial.ac.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

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?
Results article	feasibility study results in ICU patients	11/09/2019	13/09/2019	Yes	No
Results article	results in ICU patients	14/11/2019	15/11/2019	Yes	No