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Effect of continuous haemofiltration on essential micronutrient levels

Submission date
25/11/2012

Recruitment status
No longer recruiting

Registration date
10/06/2013

Overall study status
Completed

Last Edited
06/08/2018

Condition category
Urological and Genital Diseases

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

Plain English summary of protocol

Background and study aims
Seriously ill patients, with acute kidney injury (AKI), have high risk of death, especially if procedures like dialysis or haemofiltration are necessary to clear waste products. Previous studies suggest that these procedures lead to loss of nutrients from the body. It is unclear whether these losses are important and lead to nutrient deficiency. Official nutrition guidelines for patients with AKI are contradicting and don't recommend routine nutrient supplementation. It is possible that these losses are underestimated and that they may contribute to diseases and death, particularly in patients who need frequent haemofiltration for a long time. Our aim is to regularly measure vitamins, proteins and essential nutrients in critically ill patients with AKI. We hope to find out whether patients, who need regular haemofiltration, lose nutrients and whether these losses lower their levels in the blood. If our study shows that patients with AKI indeed have signs of nutrient deficiency, we will plan a future study to explore whether it is beneficial to give patients nutrient supplements routinely and whether this reduces the risk of death.

Who can participate?
Critically ill adult patients (≥ 18 years) with severe AKI can participate in this study.

What does the study involve?
Several blood tests are taken to measure essential nutrients in the blood, for over a period of 6 days. The patients are followed until discharge from the hospital.

What are the possible benefits and risks of participating?
There are no immediate benefits to the patients who are taking part. There are no risks and participating in this study does not affect the chances of making a good recovery. The patients do not receive any treatment, nutrition or drugs different from what they would receive if they did not participate in the study.

Where is the study run from?
The study is coordinated by a team at Guy's & St Thomas Hospital, London, UK.

When is the study starting and how long is it expected to run for?
The study started in early 2013 and is expected to last for 4-6 months.

Who is funding the study?
The study is funded by a research award from the European Society of Intensive Care Medicine, Belgium.

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1

Study information

Scientific Title
Effect of continuous haemofiltration on essential nutrients in critically ill patients with severe acute kidney injury

Study objectives
In patients with severe acute kidney injury (AKI) treated with continuous veno-venous haemofiltration, vitamins, trace elements and essential amino acids are lost into the filtrate and lead to nutrient deficiency.

Ethics approval required
Old ethics approval format

Ethics approval(s)
National Research Ethics Committee on the 11/03/2013, ref: 13/LO/0064

Study design
Prospective observational cohort study

Primary study design
Observational

Secondary study design
Cohort study

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
Acute kidney injury

Interventions
The following parameters will be measured:
1. Plasma levels of selenium, zinc, copper, iron, vitamins B1, B6, B12, C and D, folic acid, essential amino acids at baseline and alternate days for 6 days
2. In patients on haemofiltration: levels of selenium, zinc, copper, iron, vitamins B1, B6, B12, C and D, folic acid, essential amino acids in filtrate fluid
3. Daily measurement of serum electrolytes, liver profile, serum albumin and C-reactive protein
4. Recording of severity of illness scores and outcome (duration of stay in ICU, ICU mortality, hospital outcome)

Total duration of follow-up: until discharge from hospital or death (whichever occurs first)

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Outcomes will be assessed on a daily basis for up to 6 days after enrolment.
Dfference in plasma concentrations of essential micronutrients between patients with and without continuous veno-venous haemofiltration (CVVH)

Secondary outcome measures
1. Concentrations of trace elements, vitamins and amino acids in filtrate in patients on CVVH
2. Differences in filtrate losses between patients on continuous venovenous hemofiltration (CVVH) 30ml/kg/hr or less versus >30ml/kg/hr
3. Differences in serum levels of micronutrients and amino acids between patients on CVVH 30ml /kg/hr or less versus >30ml/kg/hr

Overall study start date
01/01/2013

Completion date
31/12/2013

Eligibility

Key inclusion criteria
Adult patients (18 years or older) in the intensive care unit with severe AKI

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
40

Key exclusion criteria
1. Pre-existing dialysis dependent renal failure
2. Life expectancy <48 hours
3. Need for total parenteral nutrition
4. Need for supplementation with intravenous multivitamins or trace elements

Date of first enrolment
01/01/2013

Date of final enrolment
31/12/2013

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
King's College London
London
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SE1 7EH

Sponsor information

Organisation
Guy's & St Thomas Hospital (UK)

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Sponsor type
Hospital/treatment centre

Website
http://www.guysandstthomas.nhs.uk

ROR
https://ror.org/00j161312

Funder(s)

Funder type
Research organisation

Funder Name
European Society of Intensive Care Medicine (Belgium) - Research Award

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	results	02/08/2018		Yes	No
HRA research summary			28/06/2023	No	No