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Furosemide and Albumin for Diuresis of Edema: a pilot study

Submission date
08/09/2013

Recruitment status
No longer recruiting

Registration date
20/09/2013

Overall study status
Completed

Last Edited
12/04/2019

Condition category
Signs and Symptoms

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

Plain English summary of protocol

Background and study aims
Many intensive care unit (ICU) patients develop edema (collection of fluid in the body) due to the fluids injected through the vein used for resuscitation. Edema has been associated with longer ICU stay and higher death rate. Thus removal of fluid is important. We aim to study whether the addition of albumin, which encourages the movement of fluid from tissues back into blood vessels, can improve the effectiveness of diuretics (drugs that increase production of urine), the basis of edema treatment.

Who can participate?
Adults admitted to the intensive care unit for any reason, who have normal blood flow and low protein levels in blood, and judged to be in need of diuresis (increased production of urine).

What does the study involve?
Participants will be randomly allocated to receive albumin or placebo (dummy), given two hours before the diuretic treatment. Study treatment will continue for 72 hours, or less if the doctors decide that further diuresis is unnecessary, serum albumin levels normalize, or the patient leaves the ICU. Study treatment will also be held if the doctors are withholding the diuretic treatment. If diuresis is resumed, the patient will restart their assigned treatment (albumin or placebo).

What are the possible benefits and risks of participating?
Patients will receive access to a potentially beneficial strategy of diuresis involving the use of albumin in addition to the usual care. There are no known cases of transmission of germs from receiving albumin despite decades of use, and the overall risk is therefore extremely remote. Some study tests will require one extra tube of blood to be collected; all other data collection and treatment is as per routine ICU care and poses no extra risk.

Where is the study run from?
This study will be conducted at intensive care units of Juravinski Hospital and Hamilton General Hospital, Hamilton, Ontario, Canada.

When is study starting and how long is it expected to run for?
Recruitment is anticipated to begin early 2014, and continue for 6-7 months, or until 50 patients are recruited.

Who is funding the study?
Hamilton Health Sciences, Canada.

Who is the main contact?
Dr Simon Oczkowski
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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
NCT02055872

Secondary identifying numbers
N/A

Study information

Scientific Title
Hyperoncotic albumin to improve diuresis in critically ill patients: a pilot randomized controlled trial

Acronym
FADE

Study objectives

We hypothesize that hyperoncotic albumin, given prior to diuretics, in edematous critically ill patients with hypoproteinemia, will improve diuresis, oxygenation, and hemodynamics. This trial is a pilot RCT to assess the feasibility of such a trial.

On 17/04/2014 the anticipated start date was changed from 01/01/2014 to 04/03/2014.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Hamilton Integrated Research Ethics Board (HIREB), 04/03/2014, ref: REB #14-002

Study design
Blinded randomized controlled trial

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
Edema

Interventions
Patients are randomized to two groups:
1. 25% albumin, 100 mL intravenous twice daily
2. Placebo, during the duration of diuresis.
Patients will be followed up for 30 days or hospital discharge, which ever is sooner.

Co-investigator:
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Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Current primary outcome measures as of 17/04/2014:
Our primary outcome is feasibility, including three components:
1. Adherence to protocol (administration of first dose of study treatment within 2 hours of furosemide; proportion of patients receiving all six doses of study treatment; absence of cointervention in placebo arm as documented in the medication administration record)
2. Randomization rate of eligible patients
3. Collection of study data (including blood chemistry, hemodynamic, and oxygenation data)

Previous primary outcome measures:
Our primary outcome is feasibility, including three components:
1. Adherence to protocol (administration of first 3 doses of study treatment, within 2 hours of furosemide, absence of cointervention in placebo arm, as documented in the medication administration record)
2. Randomization rate of eligible patients
3. Collection of study data (including blood chemistry, hemodynamic, and oxygenation data)

Secondary outcome measures
Current secondary outcome measures as of 17/04/2014:
Clinical outcomes will be secondary in this pilot study:
1. Ventilator-free days and duration of mechanical ventilation
2. Episodes interrupting treatment with furosemide
3. Fluid balance, oxygenation, hemodynamic status
4. Changes in serum electrolytes and albumin at day 1, 3, 5
5. Changes in colloid osmotic pressure at day 1, 3, 5
6. ICU and hospital mortality

Previous secondary outcome measures:
Clinical outcomes will be secondary in this pilot study:
1. Fluid balance, oxygenation, hemodynamic status
2. Serum chemistry data and blood gas measurements
3. Colloid osmotic pressure
4. ICU and hospital mortality

Overall study start date
04/03/2014

Completion date
01/01/2015

Eligibility

Key inclusion criteria
Intensive care unit patients, medical or surgical, of at least 18 years of age who meet the following criteria:
1. Hemodynamically stable for at least 24 hours
1.1. Absence of persistent (>1h) hypotension (systolic blood pressure < 90 mmHg) and

tachycardia (heart rate >110)
1.2. Not currently on vasopressors other than low dose dopamine (less than 10 mcg/kg/min)
1.3. Less than 2L crystalloid or colloid boluses or 2 units PRBCs, maintenance fluids excluded
2. Hypoproteinemia
2.1. Serum albumin < 30 mg/L, or total protein < 60 mg/L
3. Clinical decision to diurese at least 3L net fluid balance within the next 72 hours
4. For any reason, including: peripheral edema, congestive heart failure on chest x-ray, elevated CVP in the absence of right heart valvular pathology or pulmonary hypertension, elevated wedge pressure

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
50

Key exclusion criteria
1. Known pregnancy
2. Patient or surrogate unable or unwilling to consent to blood product administration, including albumin
3. History of adverse reactions or allergy to either albumin or furosemide
4. Acute kidney injury (RIFLE criteria F or greater - tripling of creatinine or creatinine >355 µmol/l (with a rise of >44) or average urine output below 0.3 ml/kg/hr for 24 hours) without any improvement in the past 24 hours, or otherwise expected to necessitate dialysis within 48 hours in the opinion of the treating physician
5. Chronic kidney injury requiring dialysis
6. Clinically documented cirrhosis
7. Clinically documented nephrotic syndrome
8. Serum sodium greater than 150 meq/L, or serum potassium less than 2.5 meq/L that cannot be treated prior to administration of study treatment
9. Inability to measure urine output and fluid balance
10. Receipt of hyperoncotic albumin within the preceding 24 hours
11. Previous enrollment in this RCT, or any other research studies which may interfere with this study
12. Estimated survival or ICU stay less than 72 hours.

Date of first enrolment
04/03/2014

Date of final enrolment
01/01/2015

Locations

Countries of recruitment
Canada

Study participating centre
Hamilton Health Sciences, General Site
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Sponsor information

Organisation
McMaster University Medical Centre (Canada)

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/05jyrng31

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Hamilton Health Sciences - New Investigator Fund (Canada)

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?
Protocol article	protocol	12/06/2014	13/06/2014	Yes	No
Results article	results	01/12/2018	12/04/2019	Yes	No