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Using the oxygen content of venous blood to guide the fluid balance of haemodialysis patients

Submission date
15/01/2015

Recruitment status
Stopped

Registration date
30/01/2015

Overall study status
Stopped

Last Edited
29/01/2018

Condition category
Urological and Genital Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol

Background and study aims
People who suffer with kidney failure need dialysis treatment 3 times a week. Each dialysis session usually lasts 4 hours, and takes place either in a hospital or in a dedicated unit outside of hospital. Dialysis treatment cleans the blood of toxins that are usually removed by kidneys. As well as removing toxins from blood, dialysis also needs to remove water from blood. One of the jobs of a Kidney Doctor is to determine how much water to remove from the blood during dialysis for each patient. This is difficult to determine and the consequences of getting it wrong can be serious. Removing too much water results in severe dehydration that can cause people to feel faint, collapse, and in extreme cases cause mini strokes. Removing too little water can result in over-hydration, which can lead to heart disease and water on the lungs. At present, there is no perfect way of establishing exactly how much water should be removed from each patient at each dialysis session. The amount removed is based on examining patients, looking for signs of excess fluid or dehydration, including looking at patient's blood pressure. This process is inexact. This study is to establish whether a simple, quick, and inexpensive blood test, taken from the dialysis machine at each session, can be used to help guide how much water should be removed from each patient during dialysis. Should this blood test work, it will reduce the side effects of patients having too much or too little water removed during dialysis, potentially leading to a better quality of life, and even life expectancy.

Who can participate?
Adults diagnosed with end stage kidney failure

What does the study involve?
Participants are first observed for three dialysis sessions. No changes to their dialysis prescription are made at this time. Measurements taken include ScvO2 (amount of oxygen in the blood), cardiac output (amount of blood pumped out by the heart), and hydration status (to see whether the patient is over or under-hydrated). These measurements are taken before and after dialysis. A quality of life questionnaire is completed at the first session. During the treatment period, patients continue to attend their normal dialysis sessions. Before each dialysis session, they are assessed by a medical member of the trial team. This assessment involves reviewing the

ScvO2 after dialysis from their previous dialysis session and examining for any evidence of fluid overload (too much fluid). If the ScvO2 is <65% and there is no evidence of fluid overload, target weight (amount of fluid removed during dialysis) will be increased by 0.5 kg. This continues until either an ScvO2≥65% is achieved, or maximum intervention has been reached. Maximum intervention refers to the point at which clinical examination precludes further increases in target weight due to risk of hypervolaemia (increase in blood volume) despite ScvO2 being <65%. A quality of life questionnaire is completed every third dialysis session during this period. After the intervention period, the participants are observed for the next 12 weeks, where ScvO2, cardiac output measurements and hydration status monitoring are all performed. Quality of life questionnaires are also completed at certain times during this period.

What are the possible benefits and risks of participating?
Monitoring ScvO2 before and after dialysis could potentially provide a means by which to protect against excessive fluid removal that can occur during haemodialysis. Hypovolaemia (decrease in amount of blood) can lead to headaches, cramps, access clotting, and falls. Additionally, hypovolaemia can result in low blood pressure, which is directly linked to increased mortality (death). Therefore the potential benefit for participants is a reduction in morbidity and mortality. The major potential risk of increasing target weight to achieve an ScvO2 of ≥65% is that of hypervolaemia. This risk can only be minimised by regular clinical assessment. The protocol requires clinician review of patients prior to any increase in target weight, which should protect against any potential harm. The protocol dictates that in the presence of clinical signs of fluid overload, no further increase in target weight will occur, and the clinician will reduce the target weight of the patient according to their assessment.

Where is the study run from?
Wessex Kidney Centre (UK)

When is the study starting and how long is it expected to run for?
May 2015 to November 2015

Who is funding the study?
Wessex Kidney Centre (UK)

Who is the main contact?
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Contact information

Type(s)
Public

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Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
PHT/2015/05

Study information

Scientific Title
Using central venous saturations >65% as an objective target for goal directed fluid management in haemodialysis patients using a tunneled venous catheter: a proof of concept trial

Acronym
SANTOS

Study objectives
We hypothesise that In patients with a post dialysis ScvO2 less than 65%, an increase in target weight will result in a increase in ScvO2 to above 65% and that rise will correspond to an increase in cardiac output.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

Study design
Proof-of-concept single-arm interventional study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Hospital

Study type(s)
Quality of life

Participant information sheet
Not available in web format, please use contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Patients with end stage renal failure receiving maintenance haemodialysis though a tunneled internal jugular dialysis catheter

Interventions
The intervention is an incremental increase in target weight by 0.5 kg per dialysis session.

Intervention Type
Other

Primary outcome measure
Post dialysis ScvO2 measured by blood gas analysis

Secondary outcome measures
1. Cardiac output using the Cheetah NICOM both pre and post dialysis as described
2. Adverse events that may occur as a result of the study intervention
3. QOL questionnaire

Overall study start date
01/05/2015

Completion date
01/11/2015

Reason abandoned (if study stopped)
Lack of staff/facilities/resources

Eligibility

Key inclusion criteria
1. Aged > 18 years old
2. Diagnosed with ESRD on maintenance haemodialysis via a central venous catheter

3. Haemoglobin >10mg/dL
4. Patient is able and willing to give informed consent

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
20

Key exclusion criteria
1. There is planned and imminent movement of the patient to a satellite haemodialysis unit
2. Individuals requiring supplementary oxygen routinely
3. The presence of a functioning fistula
4. There is planned and imminent surgery for transplantation and/or fistula formation
5. Patient survival predicted to be <3months

Date of first enrolment
01/05/2015

Date of final enrolment
01/09/2015

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Wessex Kidney Centre
Queen Alexandra Hospital
Southwick Hill Road
Portsmouth
United Kingdom
PO6 3LY

Sponsor information

Organisation
Queen Alexandra Hospital

Sponsor details
Southwick Hill Road
Portsmouth
England
United Kingdom
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04rha3g10

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Wessex Kidney Centre (UK)

Results and Publications

Publication and dissemination plan
The outcome of this study will first be reported locally following which publication in a peer-reviewed journal will be sought. Each trial participant will receive a letter informing him or her about the trial results, following the trial's conclusion.

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration