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Acute changes in metabolic parameters after bolus fluid treatment in critically ill patients

Submission date
27/06/2016

Recruitment status
No longer recruiting

Registration date
30/06/2016

Overall study status
Completed

Last Edited
30/06/2016

Condition category
Haematological Disorders

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

Plain English summary of protocol

Background and study aims
Seriously ill patients in an intensive care ward often need to have fluid therapy as part of their treatment. This is especially the case for patients who have lost blood or fluids and so do not have enough blood circling around their body (hypovolemia). Hypovolemia is seriously detrimental for patients, as it is accompanied by low cardiac output (volume of blood being pumped by the heart) and insufficient delivery of oxygen to the body's tissues. It is widely acknowledged that IV fluid administration (giving fluids through a drip) should be closely monitored in order to avoid hypovolemia or hypervolemia (fluid overload, often a consequence of treating hypovolemia incorrectly). Assessing changes in cardia output after giving fluids is a reliable method of evaluating patient's response to treatment, however this may not show the long-term consequences. The aim of this study is to investigate the effects of bolus fluid treatment (of a single, large amount of fluid through a drip) on oxygen delivery to bodily tissues.

Who can participate?
Adults with suspected hypovolemia who are being treated in ICU at CHU-Brugmann (Belgium).

What does the study involve?
For all patients, before they receive the fluid bolus (single delivery of a large amount of fluid), samples of blood from veins and arteries are taken so that the amount of oxygen present canbe measured. The results are then used to calculate the amount of oxygen being delivered to the different tissues in the body and how the tissues are using the oxygen. At the same times, a scan of the heart is performed with a special ultrasound probe to measure cardiac output.

What are the possible benefits and risks of participating?
There are no direct benefits or risks involved with participating in this study.

Where is the study run from?
CHU-Brugmann (Belgium)

When is the study starting and how long is it expected to run for?
October 2014 to March 2016

Who is funding the study?
CHU-Brugmann (Belgium)

Who is the main contact?
Dr Charalampos Pierrakos

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
1171980

Study information

Scientific Title
Evaluating the changes of cardiac output, oxygen and CO2 derived variables and lactate before and after bolus fluid treatment in critically ill patients with suspected hypovolemia

Study objectives
Metabolic parameters' changes may be used in the assessment of bolus fluid treatment (BFT) response in clinical practice.

Ethics approval required
Old ethics approval format

Ethics approval(s)
CHU-Brugmann's Ethical Committee, 14/01/2015, ref: CE2014/122

Study design
Observational cross sectional single-center study

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Hospital

Study type(s)
Other

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
Critically ill patients with suspected hypovolemia

Interventions
Patients are included in the study if they needed to receive intravenous fluids consisting of 500 ml of colloids or 1000 ml of crystalloids within 30–50 minutes. The decision to administer bolus fluids is made by the attending physician.

Cardiac index (CI) is measured by using doppler echocardiography or thermodilution (PiCCO®, EV1000®, Swan-Ganz®) just prior to the start of BFT. Arterial and central venous blood sampling and analysis are simultaneously conducted. No interventions are allowed after the start of fluid administration. At the end of fluid administration, the CI measurement and arterial and central venous blood sampling are repeated.

Intervention Type
Procedure/Surgery

Primary outcome measure
1. Oxygen consumption (VO2) is calculated using the formula arterial oxygen content-Venous oxygen content before and after bolus fluid treatment
2. Oxygen delivery (DO2) is calculated using the formula 10*CI* arterial oxygen content before and after bolus fluid treatment

Secondary outcome measures
No secondary outcome measures

Overall study start date
01/10/2014

Completion date
30/03/2016

Eligibility

Key inclusion criteria
1. Patient treated in ICU
2. Suspicion of hypovolemia that must be treated
3. Available central venous and arterial catheter
4. Available method for cardiac output measurment (thermodilution, doppler)

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
100

Key exclusion criteria
1. Aged under 18 year
2. No jugular or subclavian venous catheter and arterial catheter
3. Individuals on whom it is not possible to measure cardiac output
4. Patients receiving extracorporeal membrane oxygenation (ECMO) support
5. Receipt of interventions (i.e. introduction or increase in the dose of inotropes, changes or introduction of mechanical ventilation) within 30 minutes prior to fluid administration

Date of first enrolment
15/01/2015

Date of final enrolment
31/07/2015

Locations

Countries of recruitment
Belgium

Study participating centre
CHU-Brugmann
Place Van Gehuchten 4
Brussels
Belgium
1020

Sponsor information

Organisation
CHU-Brugmann

Sponsor details
Place Van Gehuchten 4
Brussels
Belgium
1020

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/011apjk30

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
CHU-Brugmann

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
31/12/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request