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The effects of fluid loading on cardiac response and acid-base status in the critically ill

Submission date
10/08/2015

Recruitment status
No longer recruiting

Registration date
26/08/2015

Overall study status
Completed

Last Edited
06/04/2017

Condition category
Circulatory System

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

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). These patients are often unconscious, and so fluids are given in order to help them wake up. The type of fluids that are given to these patients is a controversial subject. It is thought that different fluids have different effects on blood flow (hemodynamic parameters), as well as how acidic or alkaline the blood is (acid-base balance). The aim of this study is to investigate effects of different fluids on the lungs and heart in various patient groups including patients after cardiac and vascular surgery, and patients with sepsis and other major surgery.

Who can participate?
Adults with presumed hypovolemia with line placed in a major artery or vein to give fluids.

What does the study involve?
At the start of the study, all patients have their hemodynamic parameters (e.g. blood pressure, pulse rate) and acid-base balance measured. The fluid that will be given is chosen at random for the participants. Patients are either given normal saline (salt water) solution, saline solution containing colloids gelatine 4%, saline solution containing hydroxyethyl starch 6% or saline solution containing albumin 5%. After 90 minutes of receiving these fluids, the hemodynamic parameters and acid-base balance of the patients are measured again and compared to the original measurements.

What are the possible benefits and risks of participating?
There are no benefits of taking part in the study. There are no risks of taking part, apart from the usual risks that are related to blood tests.

Where is the study run from?
Vrije Universiteit Medical Centre (Netherlands)

When is the study starting and how long is it expected to run for?
January 2002 to December 2009

Who is funding the study?
1. Vrije Universiteit Medical Centre (Netherlands)
2. B. Braun Melsungen (Netherlands)

Who is the main contact?
Dr Angélique Spoelstra-de Man

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
The effects of fluid loading with saline, gelatine, hydroxyethyl starch or albumin solutions on cardiac response and acid-base status in the critically ill

Study objectives
Hypotheses as of 24/02/2016:
Part 1: Fluid loading in cardiac and vascular surgery:
1.1. Colloid fluid loading, by maintaining plasma COP, results in a greater plasma volume expansion and cardiac output elevation than does saline fluid loading
1.2. Colloid fluid loading would aggravate less oedema formation in the lungs than saline loading, even if complicated by increased pulmonary permeability
1.3. During fluid loading in patients with reduced systolic cardiac function as compared to those with normal function, filling pressures may be superior to filling volumes for predicting and monitoring of fluid responsiveness
1.4. The value of SvO2 as a predictor and monitor of fluid responsiveness depends on cardiac functions

Part 2: Fluid loading in septic and non-septic patients:
2.1. Fluid loading with crystalloids compared with colloids gives more pulmonary edema and the difference between crystalloids and colloids in influencing edema formation decreases when permeability is increased and the propensity for edema formation increases
2.2. Because of differences in cardiac and vascular function, fluid loading with colloids result in a greater increase in cardiac output
2.3. Cardiac dilatation is required to increase cardiac output upon fluid loading, even in dysfunctioning hearts

Previous hypotheses:
1. Colloid fluid loading, by maintaining plasma COP, results in a greater plasma volume expansion and cardiac output elevation than does saline fluid loading.
2. These fluids differ in their short term effects on acid-base balance, when roughly similar volumes are infused.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics Committee of the Vrije Universiteit Medical Centre

Study design
Single-centre randomised parallel trial.

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Other

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
Clinically hypovolemic critically ill patients

Interventions
A 90 minute filling pressure-guided fluid challenge after randomization of fluid type: normal saline and the colloids gelatine 4%, hydroxyethyl starch 6% and albumin 5%.
At baseline, patient characteristics and clinical data were recorded and measurements of hemodynamics and acid-base balance were performed. Fluids were dosed, after randomization for fluid type, during 90 min on the basis of a response in predefined filling pressure changes, as measured by the central venous or pulmonary artery catheter.

Intervention Type
Procedure/Surgery

Primary outcome measure
Primary outcome measures as of 24/02/2016:
1. The change in haemodynamic parameters of various fluid types before and after fluid loading: cardiac output, intrathoracic blood volume and extravascular lung water by the transpulmonary thermal/dye dilution technique
2. The change in pulmonary parameters of various fluid types before and after fluid loading: pulmonary capillary permeability by the pulmonary leak index for Gallium- 67 (67Ga)-labeled transferrin, and lung injury score: calculated based on the level of PEEP, the arterial PO2/FIO2 ratio, total respiratory compliance and the number of quadrants with alveolar consolidations on the chest radiograph

Original primary outcome measures:
1. The change in haemodynamic parameters of various fluid types before and after fluid loading using a variety of hemodynamic parameters varying from arterial pressures to global end diastolic volume index.
2. The difference in acid-base balance of various fluid types before and after fluid loading.

Secondary outcome measures
1. The haemodynamic effects of various fluids in septic and non-septic patients.

The following secondary outcome measure was removed on 24/02/2016:
The difference in acid-base balance between fluid types.

Overall study start date
01/01/2000

Completion date
30/12/2009

Eligibility

Key inclusion criteria
Participant inclusion criteria as of 24/02/2016:
1. Clinically presumed hypovolaemic critically ill patients, defined as a pulmonary capillary wedge pressure (PCWP) below 10 mmHg in the presence of a pulmonary artery catheter and proper wedging or a central venous pressure (CVP) below 8 mmHg at positive end-expiratory pressure (PEEP) ≤15 cm H2O and below 12 mm Hg when PEEP >15 cm H2O in the presence of a central venous catheter, and a systolic arterial pressure <110 mmHg in the absence of vasopressor therapy.
2. The presence of a pulmonary artery or central venous catheter.

Original participant inclusion criteria:
1. Clinically presumed hypovolaemia
2. Presence of a pulmonary artery or central venous catheter

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
115

Key exclusion criteria
1. Age >78 years
2. Pregnancy
3. Known anaphylactoid reactions to colloids
4. A life expectancy ofless than 24 h.

Date of first enrolment
01/01/2000

Date of final enrolment
28/10/2003

Locations

Countries of recruitment
Netherlands

Study participating centre
Vrije Universiteit Medical Centre
De Boelelaan 1117
Amsterdam
Netherlands
1081 HZ

Sponsor information

Organisation
Vrije Universiteit Medical Centre

Sponsor details
Boelelaan 1117
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Sponsor type

University/education

ROR
https://ror.org/00q6h8f30

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Vrije Universiteit Medical Centre

Funder Name
B. Braun Melsungen

Alternative Name(s)
B. Braun Melsungen AG

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Germany

Results and Publications

Publication and dissemination plan
We plan to publish the results in a peer reviewed medical journal.

Intention to publish date
01/01/2016

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Stored in repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	05/04/2017		Yes	No