

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 26/08/2015	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
Last Edited 06/04/2017	Condition category Circulatory System	<input type="checkbox"/> 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

Dr A.M. Spoelstra-de Man

Contact details

De Boelelaan 1117
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Netherlands
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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 of less 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

Amsterdam

Netherlands

1081 HZ

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