

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

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

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## Additional identifiers

### Protocol serial number

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 SvO<sub>2</sub> 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

### **Study type(s)**

Other

### **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(s)**

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 (<sup>67</sup>Ga)-labeled transferrin, and lung injury score: calculated based on the level of PEEP, the arterial PO<sub>2</sub>/FIO<sub>2</sub> 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.

### **Key secondary outcome(s)**

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.

### **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)  $\leq$ 15 cm H<sub>2</sub>O and below 12 mm Hg when PEEP >15 cm H<sub>2</sub>O 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

### **Healthy volunteers allowed**

No

### **Age group**

Adult

### **Sex**

All

### **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

**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

### 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?
<a href="#">Results article</a>	results	05/04/2017		Yes	No