

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

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		<input type="checkbox"/> Protocol
<b>Registration date</b> 30/06/2016	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
<b>Last Edited</b> 30/06/2016	<b>Condition category</b> Haematological Disorders	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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 cardiac 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 can be 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

**Protocol serial number**  
1171980

## Study information

**Scientific Title**  
Evaluating the changes of cardiac output, oxygen and CO<sub>2</sub> 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

**Study type(s)**

Other

**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(s)**

1. Oxygen consumption (VO<sub>2</sub>) is calculated using the formula arterial oxygen content-Venous oxygen content before and after bolus fluid treatment
2. Oxygen delivery (DO<sub>2</sub>) is calculated using the formula  $10 \times CI \times$  arterial oxygen content before and after bolus fluid treatment

**Key secondary outcome(s)**

No secondary outcome measures

**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 measurement (thermodilution, doppler)

**Participant type(s)**

Patient

**Healthy volunteers allowed**

No

**Age group**

Adult

**Sex**

All

**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

**ROR**

<https://ror.org/011apjk30>

## **Funder(s)**

**Funder type**

Hospital/treatment centre

**Funder Name**  
CHU-Brugmann

## **Results and Publications**

**Individual participant data (IPD) sharing plan**

**IPD sharing plan summary**  
Available on request