# Changes in middle cerebral artery blood flow velocity during the early phase of fluid resuscitation in septic intensive care patients

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bacterial infectious disorders
Study type	Observational non invasive

# Summary

### ID

NL-OMON38500

**Source** ToetsingOnline

#### **Brief title**

MCA blood flow velocity in septic patients during fluid resuscitation

### Condition

• Bacterial infectious disorders

**Synonym** blood-poisoning or septicemia, sepsis

**Research involving** Human

### **Sponsors and support**

#### Primary sponsor: Martini Ziekenhuis

1 - Changes in middle cerebral artery blood flow velocity during the early phase of  $\ldots$  14-05-2025

#### Source(s) of monetary or material Support: Ministerie van OC&W

#### Intervention

Keyword: Blood flow velocity, Fluid resuscitation, Sepsis, Transcranial Doppler

#### **Outcome measures**

#### **Primary outcome**

The main study parameter is the change in blood flow velocity in the MCA measured by TCD as a result of initial fluid resuscitation. The study is ended when 16 subjects, in whom written consent has been obtained, have successfully completed the entire study.

#### Secondary outcome

The secondary study parameter is the fluid responsiveness. This is determined by the gold standard for cardiac output determination, namely a thermodilution measurement by means of an in situ pulmonary artery catheter. Other study parameters which might intervene with the main study parameter are the blood pressure, heart frequency and CO2 level.

# **Study description**

#### **Background summary**

Sepsis remains a major challenge for the Intensive Care Unit (ICU) with high morbidity and mortality rates. Initial aggressive fluid resuscitation is recommended as first treatment step for septic patients. However, it should be strictly guided to prevent subsequent overzealous fluid therapy. It would be beneficial to have the ability to predict whether a patient will respond to fluid therapy (responder) or not (non-responder). Currently there is no such non-invasive accurate parameter with the ability to predict fluid responsiveness. In this study we aim to investigate whether the blood flow velocity in the middle cerebral artery (MCA) measured by Transcranial Doppler (TCD) can be used for this purpose. This choice is based upon the fact that the brain is the first organ to be affected by sepsis, often preceding dysfunction of other organ systems.

#### Study objective

Primary we aim to investigate whether the MCA blood flow velocity measured by TCD changes after initial fluid resuscitation in septic ICU patients, and secondly whether this MCA blood flow velocity has the ability to accurately predict fluid responsiveness in this population. Furthermore, we hope to gain more insight into the influence of sepsis on the cerebral hemodynamics.

### Study design

This prospective observational single centre study will take place at the ICU in the Martini hospital Groningen. After the diagnosis sepsis is confirmed, initial fluid resuscitation is started as soon as possible. This generally implies fluid challenges of 500 mL colloid / hour. Before and after each fluid challenge a TCD measurement of the blood flow velocity of both MCA\*s will be performed. This procedure will be repeated until the patient does not respond anymore on the fluid challenges, with a maximum of five consecutive fluid challenges. Furthermore, the blood pressure, heart rate, CO2 level and fluid responsiveness are documented.

#### Study burden and risks

The participating subjects are exposed to additional measurements. However, these are non-invasive and the associated burden is considered to be minimal. They are only subjected to a maximum of six bilateral TCD measurements (taking 10 minutes each) during the early and critical phase of fluid resuscitation. These measurements are non-invasive, safe and painless. Therefore it could be stated that the risks associated with participation are considered to be negligible and the study associated burden as minimal. The study will include temporarily incapacitated septic ICU patients, as all patients admitted to the ICU with severe sepsis or septic shock are mechanically ventilated and sedated. In order to investigate changes in MCA blood flow velocity during the early and critical phase at ICU admission, it is thus impossible to conduct the study without participation of these temporarily incapacitated septic ICU patients.

# Contacts

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3 - Changes in middle cerebral artery blood flow velocity during the early phase of ... 14-05-2025

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# **Trial sites**

### **Listed location countries**

Netherlands

# **Eligibility criteria**

Age Adults (18-64 years) Elderly (65 years and older)

### **Inclusion criteria**

ICU patient in Martini hospital Groningen Diagnosed sepsis; either severe sepsis or septic shock Noradrenaline dependency at ICU admission Pulmonary artery catheter in situ

### **Exclusion criteria**

Younger than 18 years Absence of relatives who can give informed consent on behalf of the temporarily incapacitated subject Insufficient temporal window for TCD investigation Life expectance of less than 2 days at ICU admission Intracranial infection Pre-existing brain injury Pre-existing cardiac insufficiency Immune compromised

# Study design

# Design

Study type: Observational non invasive	
Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

### Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	18-06-2013
Enrollment:	16
Туре:	Actual

# **Ethics review**

Approved WMO	
Date:	11-03-2013
Application type:	First submission
Review commission:	RTPO, Regionale Toetsingscie Patientgebonden Onderzoek (Leeuwarden)

# **Study registrations**

### Followed up by the following (possibly more current) registration

No registrations found.

## Other (possibly less up-to-date) registrations in this register

No registrations found.

5 - Changes in middle cerebral artery blood flow velocity during the early phase of ... 14-05-2025

# In other registers

### Register

ССМО

**ID** NL43415.099.13