

# Effect of stroke volume variation on parameters of peripheral perfusion in patients admitted to the Intensive Care.

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The aim of the study is to evaluate the effect of stroke volume variation on different parameters of peripheral perfusion. Additionally the relationship between these parameters will be studied.

<b>Ethical review</b>	Approved WMO
<b>Status</b>	Recruitment stopped
<b>Health condition type</b>	Other condition
<b>Study type</b>	Interventional

## Summary

### ID

NL-OMON33164

### Source

ToetsingOnline

### Brief title

Effect of stroke volume on peripheral perfusion

### Condition

- Other condition

### Synonym

non-septic shock, septic shock

### Health condition

septisch en niet-septische shock

### Research involving

Human

## Sponsors and support

**Primary sponsor:** Erasmus MC, Universitair Medisch Centrum Rotterdam

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

## Intervention

**Keyword:** peripheral perfusion, shock, stroke volume

## Outcome measures

### Primary outcome

The primary study parameter is the peripheral perfusion assessed by 1) laser doppler flowmetry, 2) sidestream dark field imaging, 3) near infrared spectroscopy, 4) photoplethysmography.

### Secondary outcome

Not applicable

## Study description

### Background summary

Intravenous administration of fluids is one of the cornerstones of treatment of hemodynamically instable patients admitted to the intensive care. The aim of fluid administration is improving tissue perfusion. The effect however is mainly assessed by the increase of cardiac output and stroke volume. Currently there is no clinical parameter which objectively evaluates the effect of fluid administration on tissue perfusion. New techniques are available which are able to assess tissue perfusion non-invasively. It is possible that one or more of these parameters are capable to guide the fluid regime on the individual needs of the patient based on the tissue perfusion.

### Study objective

The aim of the study is to evaluate the effect of stroke volume variation on different parameters of peripheral perfusion. Additionally the relationship between these parameters will be studied.

### Study design

The study will be carried out on the Intensive Care of the Erasmus Medical Center and will be carried out as a single center intervention trial.

## **Intervention**

The intervention is a passive leg raising manoeuvre. The patient is placed in a semi-recumbent position of 30 degrees. The passive leg raising is performed by elevating the patient's legs by 30 degrees and by simultaneously transferring the trunk from the semi-recumbent position to a horizontal position. Transferring the patient to the passive leg raising position transfers venous blood from the legs to the intrathoracic compartment and increases cardiac preload.

## **Study burden and risks**

The passive leg raising and measurements of peripheral perfusion will not involve risks for the subject. The passive leg raising is temporarily and the effects will not affect the subject negatively. The methods to measure peripheral perfusion are based on light with harmless wavelengths. The measurement probes will only slightly make contact with the skin and the sublingual area of the subject. The duration of the study for the individual patient is 15 minutes.

## **Contacts**

### **Public**

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## **Trial sites**

## Listed location countries

Netherlands

## Eligibility criteria

### Age

Adults (18-64 years)

Elderly (65 years and older)

### Inclusion criteria

Patients admitted to the intensive care with circulatory failure due to septic or non-septic shock.

Age > 18 years.

Use of invasive hemodynamic monitoring to assess cardiac output and stroke volume.

### Exclusion criteria

Admittance with cerebral disorders.

Elevated intra-abdominal pressure.

Ischemia of the lower extremities

Decreased left ventricular function

## Study design

### Design

**Study type:** Interventional

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

### Recruitment

NL

Recruitment status: Recruitment stopped

Start date (anticipated): 20-05-2009

Enrollment:	30
Type:	Actual

## Ethics review

Approved WMO	
Date:	05-05-2009
Application type:	First submission
Review commission:	METC Erasmus MC, Universitair Medisch Centrum Rotterdam (Rotterdam)

## 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.

### In other registers

Register	ID
CCMO	NL27359.078.09