# The Pathophysiology of Disrupted Endothelial Barrier Integrity in septic shock

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

## **Summary**

#### ID

NL-OMON21518

**Source** Nationaal Trial Register

Brief title PEBSI

**Health condition** 

Septic shock

## **Sponsors and support**

**Primary sponsor:** Amsterdam UMC, location AMC **Source(s) of monetary or material Support:** Amsterdam UMC, location AMC

#### Intervention

#### **Outcome measures**

#### **Primary outcome**

Change in transendothelial electrical resistance (TER) which will be measured using an Electric Cell-substrate Impedance Sensing device(ECIS)

#### Secondary outcome

- Change in endothelial permeability as assessed by a transwell system

- Markers of endothelial permeability and activation such as (ICAM, VCAM, occludin and PECAM)

- Markers of inflammation (IL-1, TNF, IL-6, IL-8 and vWF antigen level)

# **Study description**

#### **Background summary**

Rationale:

Sepsis is characterized by the presence of inflammatory-induced endothelial integrity loss. This reduction in endothelial barrier function results in fluid leakage associated with organ failure. Currently, there is no therapy for loss of endothelial barrier function. Evidence is increasing that plasma has protective and restorative effects on endothelial barrier integrity and function in critically ill patients.

Objective:

To investigate whether plasma restores sepsis-induced endothelial barrier integrity in an in vitro model. This will be assessed by incubating human microvascular endothelial cells with plasma samples from septic shock patients.

Study design: Single center observational study.

Intervention (if applicable): None

Study population: Patients with septic shock who are admitted to the ICU

Main study parameters/endpoints:

Changes in transendothelial electrical resistance (TER) and permeability of endothelial cells in vitro.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

The risks are negligible in this study. Blood samples will be obtained from the arterial line at quantities that are not harmful. Standard clinical care will not be altered. Participation in this study does not confer a potential benefit, but future patients with sepsis may benefit from results of this study.

#### **Study objective**

Plasma restores sepsis-induced endothelial permeabiliy as measured by transendothelial electrical resistance in an in-vitro ECIS model.

#### Study design

Patient plasma will be retrieved at 2 time points. The first assessment is within 12 hours after arriving in the ICU.

#### Intervention

not applicable

# Contacts

#### Public

Amsterdam umc, location AMC Daan van den Brink

0683542155 Scientific Amsterdam umc, location AMC Daan van den Brink

0683542155

# **Eligibility criteria**

## **Inclusion criteria**

- ≥18 years old
- Quick SOFA score  $\geq$ 2 with suspicion of infection
- MAP < 65 mmHg and lactate > 2 mmol/L despite volume resuscitation, requiring vasopressors
- Arterial catheter placement as part of standard care
- Inclusion within 12 hours after arriving on the ICU

## **Exclusion criteria**

- Absence of informed consent
- Major burns  $\geq$  18%

3 - The Pathophysiology of Disrupted Endothelial Barrier Integrity in septic shock 13-05-2025

- No arterial catheter placement  $\leq$  12 hours after arriving on the ICU

- Immunosuppressive treatment unrelated to sepsis (recent chemotherapy, chronic use of systemic steroids, methotrexate, tacrolimus, cellcept, ciclosporin, anti-TNF- $\alpha$  antibodies) - HIV infection

- Pregnancy or breast feeding

- Transfer from another hospital

# Study design

## Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

## Recruitment

NL	
Recruitment status:	Pending
Start date (anticipated):	18-10-2020
Enrollment:	30
Туре:	Anticipated

## **IPD** sharing statement

Plan to share IPD: Undecided

# **Plan description** N/A

# **Ethics review**

Positive opinion
Date:
Application type:

09-10-2020 First submission

# **Study registrations**

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

ID: 49036 Bron: ToetsingOnline Titel:

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

No registrations found.

#### In other registers

Register	ID
NTR-new	NL8962
ССМО	NL70318.018.19
OMON	NL-OMON49036

# **Study results**

#### Summary results

N/A