The Pathophysiology of Disrupted Endothelial Barrier Integrity in septic shock

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

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON21518

Bron
Nationaal Trial Register

Verkorte titel
PEBSI

Aandoening

Septic shock

Ondersteuning

Primaire sponsor: Amsterdam UMC, location AMC
Overige ondersteuning: Amsterdam UMC, location AMC

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Change in transendothelial electrical resistance (TER) which will be measured using an

Electric Cell-substrate Impedance Sensing device(ECIS)

Toelichting onderzoek

Achtergrond van het onderzoek

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.

Doel van het onderzoek

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

Onderzoeksopzet

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

Onderzoeksproduct en/of interventie

not applicable

Contactpersonen

Publiek

Amsterdam umc, location AMC
Daan van den Brink

0683542155

Wetenschappelijk

Amsterdam umc, location AMC
Daan van den Brink

0683542155

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- ≥18 years old
- Quick SOFA score ≥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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Absence of informed consent

- Major burns ≥ 18%
- No arterial catheter placement ≤ 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-α antibodies)
- HIV infection
- Pregnancy or breast feeding
- Transfer from another hospital

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Toewijzing:	N.v.t. / één studie arm
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	18-10-2020
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Voornemen beschikbaar stellen Individuele Patiënten Data (IPD)

Wordt de data na het onderzoek gedeeld: Nog niet bepaald

Toelichting
N/A

Ethische beoordeling

Positief advies

Datum:	09-10-2020
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 49036
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

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

Resultaten

Samenvatting resultaten
N/A