# Adult stem cell transplantation in severe blood poisining.

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Despite appropriate antimicrobial therapy and supportive care, septic shock is still a major cause of mortality and morbidity. Within the last decade, a broad body of evidence suggests a potential role for mesenchymal stromal cell (MSC, a...

| | |
|---|---|
| **Ethische beoordeling** | Niet van toepassing |
| **Status** | Werving nog niet gestart |
| **Type aandoening** | - |
| **Onderzoekstype** | Interventie onderzoek |

## Samenvatting

### ID

NL-OMON26490

**Bron**
NTR

**Verkorte titel**
MSC in septic shock

**Aandoening**

Mesenchymal stromal cell
Septic shock
Infection
Inflammation

### Ondersteuning

**Primaire sponsor:** Erasmus Medical Center Rotterdam
**Overige ondersteuning:** In progress

### Onderzoeksproduct en/of interventie

### Uitkomstmaten

**Primaire uitkomstmaten**

The primary outcome measure will be the time of shock reversal.

# Toelichting onderzoek

### Achtergrond van het onderzoek

Despite appropriate antimicrobial therapy and supportive care, septic shock is still a major cause of mortality and morbidity. A broad body of evidence suggests a potential role for MSC therapy to ameliorate the multifactorial process of septic shock. The major mechanisms involved herein have been indicated as (a) immunomodulation, (b) stimulation of anti-apoptotic pathways, and improvement of (c) endothelial and (d) epithelial dysfunction. In this randomized proof-of-concept single-center intervention study we will use a biologic approach to treat septic shock by using these MSCs. Our main focus will be shortening of shock reversal time. The reversal of shock is defined as the maintenance of systolic blood pressure of at least 90 mmHg without vasopressor support for at least 24 hours as described earlier. This novel model will improve understanding of disease heterogeneity and shall provide further progress in the treatment of shock associated organ failures.

### Doel van het onderzoek

Despite appropriate antimicrobial therapy and supportive care, septic shock is still a major cause of mortality and morbidity. Within the last decade, a broad body of evidence suggests a potential role for mesenchymal stromal cell (MSC, a multipotent stem cell differentiating into a variety of cell types) therapy to ameliorate the multifactorial process of septic shock. The major mechanisms involved herein have been indicated as (a) immunomodulation in terms of a shift from pro- to anti-inflammatory state, (b) stimulation of anti-apoptotic pathways, and improvement of (c) endothelial and (d) epithelial dysfunction. We want to develop a novel approach to treat septic shock by using these MSCs.

### Onderzoeksopzet

Patients will be evaluated according to protocol until 28 days after randomization. Subsequently patients will be followed until 90 days after registration.

### Onderzoeksproduct en/of interventie

Dose of 60 or 90 x 106 MSCs dependent on weight every 24 hours (first dose ≤ 6 hours of diagnosis) supplementary to the standard care in the experimental group.

Only standard care in the control group.

The expected maximum treatment duration after randomization will be 72 hours.

# Contactpersonen

## Publiek

Erasmus Medical Center Rotterdam<br>
Department of Intensive Care Adults<br>
P.O. Box 2040
N. Kusadasi
Rotterdam 3000 CA
The Netherlands

## Wetenschappelijk

Erasmus Medical Center Rotterdam<br>
Department of Intensive Care Adults<br>
P.O. Box 2040
N. Kusadasi
Rotterdam 3000 CA
The Netherlands

# Deelname eisen

## Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Patients ≥18 years;

2. ≤6 hours of admission;

3. Having the diagnosis of septic shock.

## Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Age >75 years;

2. Moribund and where death is imminent;

3. Pregnancy;

4. Inflammatory diseases from any other origin then sepsis;

5. Chronic pulmonary or kidney disorders;

6. Active malignancies;

7. Single organ or other stem cell transplantations;

8. Participation in other clinical intervention studies.

# Onderzoeksopzet

## Opzet

| | |
|---|---|
| Type: | Interventie onderzoek |
| Onderzoeksmodel: | Parallel |
| Toewijzing: | Gerandomiseerd |
| Blindering: | Open / niet geblindeerd |
| Controle: | Geneesmiddel |

## Deelname

Nederland

| | |
|---|---|
| Status: | Werving nog niet gestart |
| (Verwachte) startdatum: | 01-09-2013 |
| Aantal proefpersonen: | 30 |
| Type: | Verwachte startdatum |

# Ethische beoordeling

Niet van toepassing

| | |
|---|---|
| Soort: | Niet van toepassing |

# Registraties

## Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

## Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

## In overige registers

| Register | ID |
|---|---|
| NTR-new | NL3333 |
| NTR-old | NTR3495 |
| Ander register | Erasmus MC Rotterdam : 2011-MSC-1 |
| ISRCTN | ISRCTN wordt niet meer aangevraagd. |

# Resultaten

**Samenvatting resultaten**
N/A