Adult stem cell transplantation in severe blood poisining.

No registrations found.

Ethical review	Not applicable
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON26490

Source
NTR

Brief title
MSC in septic shock

Health condition

Mesenchymal stromal cell
Septic shock
Infection
Inflammation

Sponsors and support

Primary sponsor: Erasmus Medical Center Rotterdam
Source(s) of monetary or material Support: In progress

Intervention

Outcome measures

Primary outcome

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

Secondary outcome

1. The infusion and post-transfusion related toxicity;

2. Immune cell response;

3. Mortality;

4. Length of stay;

5. Pulmonary function;

6. Sepsis severity;

7. Microcirculatory disturbances.

Study description

Background summary

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.

Study objective

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.

Study design

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

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

1. Patients ≥18 years;

2. ≤6 hours of admission;

3. Having the diagnosis of septic shock.

Exclusion criteria

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.

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2013
Enrollment:	30
Type:	Anticipated

Ethics review

Not applicable
Application type: Not applicable

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
NTR-new	NL3333
NTR-old	NTR3495
Other	Erasmus MC Rotterdam : 2011-MSC-1
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A