Mesenchymal stromal cell (MSC) transplantation in septic shock.

Published: 22-02-2013
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Evaluation of therapeutic safety and clinical efficacy of MSC transplantation in septic shock.

Ethical review	Not approved
Status	Will not start
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON39173

Source
ToetsingOnline

Brief title
MSC in septic shock

Condition

- Other condition
- Immune disorders NEC
- Ancillary infectious topics

Synonym
septic shock and severe blood poisoning

Health condition

septisch shock

Research involving
Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam
Source(s) of monetary or material Support: subsidie zal worden aangevraagd bij ZonMw,fondsen worden benaderd

Intervention

Keyword: Immunomodulation, Inflammation, MSC, Sepsis

Outcome measures

Primary outcome

Primary parameters: the dose of norepinephrine and the systolic blood pressure

at specified time points.

The primary outcome measure: shock-reversal time.

Definition: 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.

(See section 8.1 of the research protocol)

Secondary outcome

Secondary endpoints:

1. treatment related toxicity

2. systemic immune cell response

3. disease severity and outcome

(See for detailed description section 8.2 and 8.3 of the research protocol)

Study description

Background summary

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

Evaluation of therapeutic safety and clinical efficacy of MSC transplantation in septic shock.

Study design

Randomized proof-of-concept single-center intervention study.

Intervention

Infusion: 60 or 90 x 106 MSCs, dependent of weight, supplementary to the standard care in the experimental arm and only standard care in the control arm.

Frequnecy: daily for 3 days (first dose within 6 hours of diagnsosis)

Study burden and risks

The burden associated with participation consists of MSC infusion and blood sampling at specified time points.

The theoretical and on experimental studies based risks associated might be the MSC differentiation in unwanted cell types, the stimulation of growth of previously undetected tumour and the development of ectopic grafting. To our knowledge, in human studies, there were no (serious) adverse events and adverse side effects in the post-infusion period. Most of the human studies described taste and smell abnormalities during infusion.

Considering the life-threatening nature of septic shock with multiple organ failure, we expect benefit in terms of shock-reversal, that can be seen as the forerunner of survival from this deadly syndrome.

(See for detailed information section 6.4 and Appendix A of the research protocol)

Contacts

Public
Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230
Rotterdam 3015 CE
NL
Scientific
Erasmus MC, Universitair Medisch Centrum Rotterdam

's Gravendijkwal 230
Rotterdam 3015 CE
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients between 18 and 75 years, fulfilling the criteria for pneumonia septic shock. ;(see chapter 4.2 and Appendix B of the research protocol)

Exclusion criteria

Moribund and where death is imminent, pregnancy, inflammatory diseases from any other origin then sepsis, chronic pulmonary or kidney disorders, active malignancies, single organ or other stem cell transplantations and participation in other clinical intervention studies. ;(see section 4.3 of the research protocol)

Study design

Design

Study phase:	2
Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Open (masking not used)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Will not start
Enrollment:	30
Type:	Anticipated

Medical products/devices used

Product type:	Medicine
Generic name:	Somatic cels allogenic

Ethics review

Approved WMO

Date:	22-02-2013
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

Not approved	
Date:	18-04-2013
Application type:	First submission
Review commission:	CCMO: Centrale Commissie Mensgebonden Onderzoek (Den Haag)

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
EudraCT	EUCTR2011-006358-98-NL
CCMO	NL39348.000.13