Microangiopathy after autologous hematopoietic stem cell transplantation in systemic sclerosis

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Autoimmune disorders
Study type	Observational invasive

Summary

ID

NL-OMON46923

Source
ToetsingOnline

Brief title
MICAST

Condition

- Autoimmune disorders

Synonym
scleroderma, systemic sclerosis

Research involving
Human

Sponsors and support

Primary sponsor: Leids Universitair Medisch Centrum
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: microangiopathy, nailfold capillaromicroscopy, stem cell transplantation, systemic sclerosis

Outcome measures

Primary outcome

Microangiopathy will be assessed by NCM. NCM pattern will be classified as

early, active or late. Capillary density, number of giants and number of

micro-haemorrhages will be observed. Additionally, PRINCE, MES scores and mNEMO

scores will be calculated.

Secondary outcome

To assess clinical response, a physician global assessment for treatment

response will be performed per organ system, the Medsger SSc severity score

will be assessed, and the HAQ-DI will be calculated.

Study description

Background summary

The results of clinical trials evaluating the effect of autologous HSCT in SSc were encouraging. However, treatment related mortality is high and not all patients benefit from HSCT. Therefore, more research is needed to understand the biological effect of autologous HSCT on SSc. Uncontrolled case series indicate reversibility of microangiopathy after autologous HSCT.

Study objective

The primary objective of this study is to describe the effect of HSCT on the microangiopathy of SSc patients by using nailfold capillary microscopy (NCM). The secondary objective is to investigate the correlation between NCM findings and clinical response.

Study design

Prospective nested case-control study

Study burden and risks

Participants will be invited to visit the hospital once for an NCM procedure which is not invasive or painful and takes approximately 15-30 minutes. When auto-antibody status is not determined within the last 12 months before the current visit, additionally a serum sample will be obtained. Relevant demographic and clinical information are collected from the biobank Systemic sclerosis database. No risks are associated with the participation in this study.

Contacts

Public
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL
Scientific
Leids Universitair Medisch Centrum

Albinusdreef 2
Leiden 2333 ZA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

1. Age above 18
2. Systemic sclerosis meeting the American Rheumatism Association criteria (1980)
3. Severe systemic sclerosis with:
a. disease duration < 4 years with modified Rodnan skin score >15 and respiratory involvement
b. disease duration < 2 years with modified Rodnan skin score >20 and ESR > 25 mm/1st hour and/or Hb < 11 g/dL
4. Written informed consent
5. Able and willing to perform additional nailfold capillaromicroscopy at the outpatient clinic of the LUMC

Exclusion criteria

none

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-01-2017
Enrollment:	100
Type:	Actual

Ethics review

Approved WMO Date:	19-01-2017
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	13-03-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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
CCMO	NL59376.058.16

Study results

Date completed:	05-11-2018
Actual enrolment:	81