Biomarkers in Systemic Sclerosis

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Construction of a biobank with peripheral blood and skin biopsies from patients with SSc, to evaluate (new) antigens and/or (new) antibodies and/or RNA expression profiles and to correlate these findings with clinical parameters (i.e. disease...

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

Summary

ID

NL-OMON30650

Source
ToetsingOnline

Brief title
Biomarkers in SSc

Condition

- Autoimmune disorders
- Connective tissue disorders (excl congenital)

Synonym
scleroderma

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Systemic Sclerosis

Outcome measures

Primary outcome

To construct a biobank with peripheral blood and material from skin biopsies from patients with SSc to evaluate (new) antigens and/or (new) antibodies and to compare these between subsets of SSc, and to correlate these findings to disease characteristics like subsets of SSc (limited or diffuse cutaneous SSc, limited SSc), disease duration, presence and extend of organ involvement (skin, lung, heart, renal, gastrointestinal involvement). Studyparameters/ endpoints will be determined depending hypotheses of experiments.

Secondary outcome

Secundary studyparameters/ endpoints will be determined depending hypotheses of experiments.

Study description

Background summary

Systemic sclerosis (SSc) is a potentially devastating and progressive disease with high mortality and morbidity. Its pathogenesis is still not completely understood. A better understanding of the pathogenesis of SSc and the formulation of valid and testable hypotheses might provide foundations for the development of effective therapeutic agents. The construction of a biobank of peripheral blood and skin biopsies from a large cohort of SSc patients provides material for testing such hypotheses.

Study objective

Construction of a biobank with peripheral blood and skin biopsies from patients with SSc, to evaluate (new) antigens and/or (new) antibodies and/or RNA expression profiles and to correlate these findings with clinical parameters (i.e. disease duration, type of SSc) and skin/ organ involvement (lung, heart, renal).

Study design

Observational (nested case-control and cohort)

Study burden and risks

The risk and burden to the subject will be in proportion to the potential value of the research, as patients with SSc continue to have a poor prognosis without the perspective of being cured. Research for better delineation of the pathogenesis of the disease may lead to the development of potential avenues, such as cytokine-receptor decoys, that could be explored as therapeutic targets for this disease.
Specified risk and burden: Number of extra institutional visits: none. Number of blood samples: SSc patients: 1 per year (8 tubes (@ 30 ml) per occasion). Skin biopsies: SSc patients with diagnosis < 4 years: baseline, 1, 2, 4 years after diagnose with maximum of 10 biopsies. SSc patients with diagnosis > 4 years and iPAH patients: 1x 3 biopsies. Risks associated with investigation: in rare cases (< 1%), delayed wound healing in SSc affected skin after biopsy.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Written informed consent

Exclusion criteria

None

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-07-2007
Enrollment:	215
Type:	Actual

Ethics review

Approved WMO

Date:	13-06-2007
Application type:	First submission

Review commission: METC Amsterdam UMC

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	NL15478.029.06