Linking inflammation and hypoxia to disease subtype and course in systemic sclerosis by exploratory analysis of SMAD-linker domains study

Published: 30-08-2016
Last updated: 14-04-2024

This investigation aims to investigate connective tissue fibroblast activation in detail in the inflamed fibrotic connective tissue. By analyzing these cells in detail we hope to understand better how they are activated, so we can develop better and…

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

Summary

ID

NL-OMON43179

Source
ToetsingOnline

Brief title
LISS

Condition

- Autoimmune disorders
- Connective tissue disorders (excl congenital)

Synonym
systemic sclerosis - scleroderma

Research involving
Human

Sponsors and support

Primary sponsor: reumatologie
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: linker, prognosis, SMAD, systemic sclerosis

Outcome measures

Primary outcome

Amount of activated SMAD proteins in fibroblasts

Secondary outcome

effect of SMAD inhibitors on fibroblast activation.

activation of other SMAD activating kinases.

Study description

Background summary

Systemic sclerosis is a rare, invalidating disease that manifests by inflammation and fibrosis of subcutaneous connective tissue, organs and blood vessels. Treatment options are very limited because of very limited understanding of pathogenesis. Therefore, it is important to gain more innsight in the cause of the condition through scientific analyses to develop new treatments. Systemic sclerosis is considered to be an autoimmune disease in which immune cells attack self tissues in the connective tissue and blood vessels. It is unknown how this inflammatory response results in fibrosis and vessel damage. Likely, specific inflammatory mediators and low oxygen levels play a role that lead to abnormal activation of connective tissue cells.

Study objective

This investigation aims to investigate connective tissue fibroblast activation in detail in the inflamed fibrotic connective tissue. By analyzing these cells in detail we hope to understand better how they are activated, so we can develop better and more precise treatments.

Study design

one visit study with interview, physical examination, blood sampling to measure disease activity. Extra blood sampling of 100 ml. 1 skin biopsy of severely fibrotic area and 1 biopsy of mildly fibrotic area.

Study burden and risks

A proportion of patients experiences a small hematoma after skin biopsy. the overall risk is assessed low because of a moderate chance of minor tissue damage.

Contacts

Public
Selecteer

Geert Grooteplein-zuid 10
Nijmegen 6525GA
NL
Scientific
Selecteer

Geert Grooteplein-zuid 10
Nijmegen 6525GA
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

-10 patients with limited systemic sclerosis (SSc), 10 with early diffuse SSc, 10 with established diffuse SSc without severe vasculopathy, 10 with established diffuse SSc with severe vasculopathy.
-18 years or older

Exclusion criteria

active inflammatory or infectious co-morbid disease

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):	15-11-2016
Enrollment:	40
Type:	Actual

Ethics review

Approved WMO Date:	30-08-2016
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	09-10-2017
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL57997.091.16