Assessing the frequency, phenotype and function of plasmacytoid dendritic cells and T cells in blood and skin of patients with skin fibrosing disorders

Published: 14-10-2013 Last updated: 25-04-2024

To investigate the difference in number, phenotype and function of plasmacytoid dendritic cells and T cells in and between patients with SSc, LS and EF and between patients with these diseases and healthy controls / patients with psoriasis.

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

Summary

ID

NL-OMON47886

Source ToetsingOnline

Brief title

Analysis of immune cells in skin fibrosing disorders

Condition

- Autoimmune disorders
- Connective tissue disorders (excl congenital)
- Skin and subcutaneous tissue disorders NEC

Synonym

Systemic sclerosis - scleroderma / Localized scleroderma - morphea / Eosinophilic fasciitis - ?

Research involving

Human

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Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht **Source(s) of monetary or material Support:** project Reumafonds

Intervention

Keyword: Localized scleroderma, plasmacytoid dendritic cell, Systemic sclerosis, T-cell

Outcome measures

Primary outcome

Number, phenotype and function of plasmacytoid dendritic cells and T cells in

the skin and blood of patients suffering from SSc, LS or EF and in healthy

controls / patients with psoriasis.

Secondary outcome

not applicable

Study description

Background summary

Systemic sclerosis (SSc) is a multifactorial autoimmune disorder eventually causing fibrosis of the connective tissue such as skin and internal organs. There is no effective treatment for SSc giving rise to a high unmet need. Hence, further research to improve prognosis for these patients is highly justified. Recent evidence from our group suggests an initial pathologic event in the cells of the immune system in contrast to the current paradigm were fibroblast are considered the primary cause. In fact, recent data shows an increase of plasmacytoid dendritic cells (pDC) with an aberrant biology both in the circulation and lesional skin of SSc patients. In addition, we discovered new biomarkers, which are present in the early phase of the disease and predict disease progression. However, how these pDCs and biomarkers orchestrate skin fibrosis are largely unknown. More knowledge on this would not only provide more insight into the pathogenic circuitry in SSc but also in other fibrosing skin disorders for instance localized scleroderma (LS, morphea, linear scleroderma) and eosinophilic fasciitis (EF). Most of the current research in these fibrosing diseases is done with immune cells derived from the blood. Investigating the immune cells present in the skin has the major advantage to

study the local processes in the affected areas.

Study objective

To investigate the difference in number, phenotype and function of plasmacytoid dendritic cells and T cells in and between patients with SSc, LS and EF and between patients with these diseases and healthy controls / patients with psoriasis.

Study design

Observational, cross-sectional study.

Study burden and risks

There is no direct benefit for the participants in this study. A small scar will develop at the site of the biopsy, this small scar will gradually fade in color. Performing a biopsy entails a slight risk of hemorrhage and infection. Bleeding of the skin can usually be stopped by simple compression of the wound or by placing a small sponge in the wound. The risk of infection is generally considered as relatively low. The risks of a venapuncture are generally considered to be very low, it is possible that a haematoma develops at the site of the puncture.

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

-Age range: 18 - 75 years -Diagnosed with systemic sclerosis, localized scleroderma, eosinophilic fasciitis or psoriasis.

Exclusion criteria

--Current use of coumarin derivatives
-Current use of cyclophosphamide
-IV corticosteroids in the last 14 days for inclusion
-Age <=17 years
-Patients with contra-indications for undergoing a skin biopsy (for example allergic to topical anesthetics)

Study design

Design

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

Recruitment

NL

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Recruitment status:	Recruitment stopped
Start date (anticipated):	16-12-2014
Enrollment:	150
Туре:	Actual

Ethics review

Approved WMO	
Date:	14-10-2013
Application type:	First submission
Review commission:	METC NedMec
Approved WMO	
Date:	27-10-2014
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	
Date:	12-12-2017
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO	
Date:	29-05-2019
Application type:	Amendment
Review commission:	METC NedMec

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.

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In other registers

Register

ССМО

ID NL43660.041.13