B cell Activation in Sjögren's Syndrome, Cutaneous Lupus Erythematodus and Systemic Sclerosis Tissues Analysis 2

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

Summary

ID

NL-OMON55626

Source
ToetsingOnline

Brief title
BASTA2

Condition

- Autoimmune disorders
- Joint disorders

Synonym
Cutaneous Lupus Erythematodus, Sjögren, Systemic Sclerosis

Research involving
Human

Sponsors and support

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

PPS,Reumanederland;GSK;Galapagos

Intervention

Keyword: B cell, Cutaneous Lupus Erythematodus, Sjögren's syndrome, Systemic sclerosis, T cell

Outcome measures

Primary outcome

To determine the difference in expansion, reactivity, function and regulation

of autoreactive B and T cell clones

compared to other B and T cell clones in inflammatory tissues of SSj versus CLE

and SSc patients.

Secondary outcome

not applicable

Study description

Background summary

Sjögren's syndrome (SSj), cutaneous lupus erythematodus (CLE) and systemic sclerosis (SSc) are chronic inflammatory
conditions characterized by inflammation and damage of tissues. The precise cause of SSj, CLE and SSc are unknown.
On the one hand, SSj, CLE and SSc have been considered to be autoimmune diseases, in which autoreactive B and
T cell clones recognize tissue autoantigens, expand and drive tissue destruction. On the other hand, SSj, CLE and SSc
have been thought to be caused by primary inflammatory activation of innate immune cells, through for instance direct
infection or stimulation by toxins released by commensal microbes, resulting in production of inflammatory mediators
that attract immune cells among which a mixed repertoire of allo- and autoreactive B and T cells. In this context, locally
expanded B and T cell clones might exert proinflammatory or immunoregulatory functions.

Study objective

The objective of this study is to investigate of inflammatory tissues of patients with SSj, CLE and SSc contain autoreactive B and T cell expansions that are differently activated compared to other B and T cell expansions in patients with SSj, CLE and SSc.

Study design

translational investigation in a transversal cohort

Study burden and risks

SSj, CLE and SSc patients will be seen for two or three study visits. At the first visit they will be asked questions about their disease and have to fill out two questionaires. Hundred milliliters of blood will be drawn. For SSj patients at the second study visit a biopsy of an inflamed salivary gland will be taken, similar to that taken for diagnostic purposes, under local anaesthetics. For SSc and CLE patients during the second visit a skin biopsy will be taken from involed and non-involved skin.
Patients with SSj, CLE and SSc will be asked for separate consent to take a lymph node biopsy. This will be performed at a third study visit. The lymph node biopsy will be taken under ultrasound guidance and lokal anaesthesics. All biopsy procedures are performed on routine basis in clinical practice. Furthermore, we have experience in taking lymph node biopsies for research purposes in patients with rheumatic diseases. All biopsy procedures are tolerated well. After both procedures a local hematoma may occur.

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

Inclusion criteria for Sjögren's syndrome (SSj) patients are: diagnosis of primary SS according to the European American consensus group criteria, grade 3 or 4 Chisholm score in salivary gland biopsy and presence of antinuclear (ANA), anti-SSA and/or anti-SSB antibodies.
Inclusion criteria for CLE patients are: diagnosis of subacute cutaneous lupus erythematosus (SCLE) or SLE with cutaneous lupus according to the Düsseldorf classification criteria . Presence of anti-nuclear (ANA), anti-SSA and/or anti-SSB antibodies. Active skin disease as assessed by the treating physician.
Inclusion criteria for the SSc patients are: diagnosis of early diffuse cutaneous SSc, according to the VEDOSS criteria defined as having a diffuse skin involvement, presence of anti-nuclear antibodies (ANA) a disease duration (from fìrst non-ñaynaud symptom) of < 3 years and progressive disease as defined by an increase in mean Rodnan skin score (hnSS) > 10 points or > 25% in the past year. Patients will be selected with skin involvement of the legs, which allows the analysis of an inguinal lymph node as locoregional lymph node.

Exclusion criteria

Exclusion criteria for both SSj patients and SSc patients are presence of active concurrent inflammatory or infectious condition, current or previous use of biologic treatment, previous other systemic autoimmune disease, diagnosis or positive serology for hepatitis C or Human lmmunodeficiëncy Virus.

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

Recruitment status:	Pending
Start date (anticipated):	01-06-2019
Enrollment:	20
Type:	Anticipated

Ethics review

Approved WMO Date:	16-05-2019
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	26-09-2022
Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	24-01-2023
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	12-03-2024
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	NL67672.091.22