What role do immune cells have in the development and persistence of Sjögren's syndrome?

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

Summary

ID

NL-OMON33948

Source
ToetsingOnline

Brief title
Role of immune cells in Sjögren's Syndrome.

Condition

- Autoimmune disorders

Synonym
(primary) Sjögren's syndrome, sicca syndrome

Research involving
Human

Sponsors and support

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

Intervention

Keyword: IL-7(Receptor), immunopathology, Sjögren's syndrome, T cells

Outcome measures

Primary outcome

Primary immunological parameters:

1. activation of several types of immune cells before and after stimulation with and without blockade of this stimulation (read-out measurements: proliferation, activation markers, cytokine production and other inflammatory mediators)
2. cytokine en biomarker profiles in serum and saliva.

These parameters will be compared between Sjögren patiënts, non-Sjögren sicca patients, and healthy controls as outcome measurements.

Secondary outcome

These parameters will be compared between Sjögren patiënts and non-Sjögren sicca patients as outcome measurements.

3. General disease parameters, which will be measured during their annual visit to the outpatient clinic of the UMC Utrecht. (e.g. immunoglobulines, ESR, leukocyte count).
4. unstimulated and stimulated salivary flow
5. unstimulated tear production
6. brief impression of general fatigue symptoms, and subjective dryness of

mouth and eyes with the use of questionnaires

Study description

Background summary

Patients with Sjögren's syndrome (pSS) suffer from several invalidating symptoms, such as dryness, fatigue, and muscle- and joint complaints, caused by a chronic activation of the immune system. An increased presence of different types of immune cells is found within the salivary and lacrimal glands. There is no cure for Sjögren's Syndrome, patients can only be treated symptomatically. It is believed that a certain subset of T cells (pro-inflammatory effector T cells) might play an important role in the inflammation and glandular tissue destruction found in Sjögren's Syndrome. Recently, it was discovered that these effector T cells can be identified through a cell surface marker, the IL-7 receptor.
IL-7, a pro-inflammatory cytokine, that can potently activate these T cells, is found to be elevated in the exocrine tissue of patients with Sjögren's Syndrome. Eventually, inhibition of effector T cells through blockade of the IL-7 receptor might be possible, which could lead to a more specific inhibition of local inflammatory processes in the exocrine glands.

Study objective

This research project aims to investigate the interaction between systemic immune cells and cells from the glandular tissue of patients with Sjögren's syndrome and sicca syndrome. We hope to obtain more insight in the cause and persistence of the inflammatory processes. This could lead to a better understanding of the aetiology and extent of this disease and possibly a better therapeutical stratification of patients with pSS. Our study will eventually contribute to the search for new treatment regimes, particularly towards specific immunomodulation of Sjögren's Syndrome.

Study design

Cross-sectional study. This research project does not include a 'clinical trial'. Additionally, no intervention strategy will be applied. As part of their regular healthcare, patients wil visit the reumatologist at the outpatiënt clinic once, twice or several times a year.
In case they have several regular visits a year, it might be possible that we will ask patients to donate their blood twice a year.

Study burden and risks

This study will not involve any direct advantages for the participants. Participation to this research might lead to more insight in and a better understanding of Sjögren's Syndrome. The major disadvantages:
Group 1: this group will undergo an extra venapunction, before the labial salivary gland biopsy procedure. Furthermore, they will be asked to donate saliva by spitting in a plastic cup and answering 2 short questionnaires. These procedures will involve a slight burden for the patient and will cost 30 minutes of the patient's time.

Groep 2: similar as for group 1, with the exception of an extra venapunction. Extra blood will be collected during the scheduled venapuncture as part of the patient's annual visit to the outpatient clinic.

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

Group 1: Patients (>= 18 yr) with sicca complaints, with a suspicion of Sjögren's syndrome, and that will undergo lipbiopsy as a diagnostic tool
Group 2: Patients (>= 18 yr), who are diagnosed with Sjögren's syndrome, according to the revised American-European consensus group (Vitali, Bombardieri et al. 2002), with a lymphocytic focus score >=1 on minor salivary gland biopsy. Patients (>= 18 yr), who are diagnosed with non-Sjögren's sicca syndrome, with a lymphocytic focus score of 0 on minor salivary gland biopsy.
Healthy controls (>= 18 yr), recruited from the Minidonordienst (inhouse blood donating service) of the UMC Utrecht, who are free of the use of immunosuppressive drugs.

Exclusion criteria

Patients with any other causes of dryness will not be included in this study. Individuals that are not free of the use of immunosuppressive drugs at least 3 months prior to this study.

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:	Recruitment stopped
Start date (anticipated):	06-05-2010
Enrollment:	400
Type:	Actual

Ethics review

Approved WMO Date:	07-07-2009
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL25380.041.08