B cell Activation in Sjögren*s Syndrome Tissues Analysis

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

Summary

ID

NL-OMON42327

Source
ToetsingOnline

Brief title
BASTA

Condition

- Autoimmune disorders
- Joint disorders

Synonym
rheuma, Sjögren

Research involving
Human

Sponsors and support

Primary sponsor: Radboudumc
Source(s) of monetary or material Support: Ministerie van OC&W,ZonMw Klinisch Fellowship

Intervention

Keyword: B cell, function, reactivity, regulation, Sjögren's syndrome

Outcome measures

Primary outcome

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

of autoreactive B cell clones compared to aother B cell clones in inflammatory

tissues of SS patients and lymphoid tissue of non-inflammatory controls.

Secondary outcome

not applicable

Study description

Background summary

Sjögren*s syndrome (SS) is a chronic inflammatory condition characterized by inflammation of exocrine glands, frequently accompanied by inflammation of other tissues. The precise cause of SS unknown. On the one hand, SS has been considered to be an autoimmune disease, in which autoreactive B cell clones recognize glandular autoantigens, expand and drive tissue destruction. On the other hand, SS has been thought to be caused by primary inflammation of glandular epithelial cells, through for instance viral or post-viral inflammatory mechanisms, inducing apoptosis and production of inflammatory mediators that attract immune cells among which a mixed repertoire of allo- and autoreactive B cells. In this context, locally expanded B cell clones might exert proinflammatory or immunoregulatory functions.

Study objective

The objective of this study is to investigate of inflammatory tissues of patients with SS contain autoreactive B cell expansions that are differently activated compared to other B cell expansions in patients with SS and in persons with salivary gland complaints not caused by SS.

Study design

translational investigation in a transversal cohort

Study burden and risks

Cases and controls 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 cases 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 controls during the second visit, instead of a salivary gland biopsy an ultrasound guided biopsy of a cervical lymph node, which are also involved in the SS disease process, will be taken. The lymph node biopsy will be taken under ultrasound guidance and lokal anaesthesics. Patients with SS will be asked for separate consent to take a lymph node biopsy next to a salivary gland biopsy. This will be performed at a third study visit. Both 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. Both biopsy procedures are tolerated well. After both procedures a small local hematoma may occur.

Contacts

Public
Radboudumc

Geert Grooteplein-Zuid 10
Nijmegen 6525GA
NL
Scientific
Radboudumc

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

Inclusion criteria for Sjögren's syndrome (SS) 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 anti-nuclear (ANA), anti-SSA and/or anti-SSB antibodies. Inclusion criteria for the non-SS sicca patients are: persistent sensation of dry eyes and dry mouth with no objective evidence of SS, including low Chisholm score in glandular biopsy (grade 0 or 1), absence of ANA, anti-SSA, anti-SSB, anti-immunoglobulin G (rheumatoid factor) and anti-cyclic citrullinated peptide antibodies.

Exclusion criteria

Exclusion criteria for both SS patients and non-SS sicca 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 Immunodeficiëncy 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: Recruitment stopped

Start date (anticipated):	01-11-2015
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO Date:	24-08-2015
Application type:	First submission
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	NL53098.091.15