Lipbiopsie bij Sjogrens Syndrome.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON22127

Source
NTR

Brief title
Sjogrens lipbiopsie

Health condition

Sjogrens Syndroom
auto-immuun aandoeningen
Xerostomie

Sponsors and support

Primary sponsor: Academisch Medisch Centrum, div. Immunology and Rheumatology
Source(s) of monetary or material Support: Academisch Medisch Centrum, div. Immunology and Rheumatology

Intervention

Outcome measures

Primary outcome

Obtained material will be used to elucidate primarily the B-cell pathogenesis of Sjogren's Syndrome. Using immunohistochemistry, RNS and protein analysis, the B-cel receptor (BCR), T-cell receptor (TCR), a B-cell stimulating cytokine (APRIL) and the interaction between different immune cell populations and cytokines will be studied

Secondary outcome

N/A

Study description

Background summary

Country of recruitment: The Netherlands.

In all patients undergoing diagnostic lower lip biopsies, salivary gland tissue will be collected and studied.

Study objective

To gain more insight into the pathogenetic processes involved in Sjogrens Syndrome(SS) bij analyzing the infiltrate and structural changes in salivary glands of SS patients and compare these findings to those in other (aspecific) inflammatory and non-inflammatory salivary gland diseases.

Study design

One, after lipbiopsy.

Intervention

In all patients undergoing diagnostic lower lip biopsies, salivary gland tissue will be collected and processed using a standard protocol for formalin fixation to allow standard histological evaluation for diagnostic purposes. Samples will also be frozen in Tissue-Tek OCT compound for immunohistochemistry (IHC) or snap frozen for PCR, micro-array, T Cell Receptor (TCR) and B Cell Receptor (BCR) analysis, and protein expression analysis. Tissues will be analyzed using these techniques for exploratory analysis in relationship to the pathogenesis of SS.

Contacts

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Eligibility criteria

Inclusion criteria

Patients undergoing lower lip biopsies for diagnostic purposes.

Exclusion criteria

N/A

Study design

Design

Study type:	Observational non invasive
Intervention model:	Parallel
Allocation:	Non controlled trial
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-11-2010
Enrollment:	200
Type:	Anticipated

Ethics review

Positive opinion

Date:	02-08-2010
Application type:	First submission

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
NTR-new	NL2339
NTR-old	NTR2446
Other	MEC AMC : 10/011
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A