Fatigue in patients with primary Sjogren’s syndrome

No registrations found.

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

Summary

ID

NL-OMON24290

Source
NTR

Health condition

Primary Sjögren's syndrome (pSS)
Fatigue
fMRI
Cytokines

Primaire syndroom van Sjögren
Vermoeidheid
fMRI
Cytokines

Sponsors and support

Primary sponsor: University Medical Center Groningen
Source(s) of monetary or material Support: University Medical Center Groningen (sponsor)

Intervention

Outcome measures

Primary outcome

- Maximal force of the first dorsal interosseous (FDI) muscle

- Force decline during the fatiguing task

- Muscle activation during the fatiguing task

- Questionnaire scores

- Changes in cortical activation during the fatiguing task (functional MRI data).

Secondary outcome

- Ectromyographic activity of the FDI muscle during the motor tasks

Study description

Study objective

Fatigue in patients with primary Sjögren's syndrome can be explained by force decline during a fatiguing task, muscle activation, mood, and the serum levels of proinflammatory cytokines.

Patients with primary Sjögren's syndrome will show attenuated task-related cortical activation compared to control subjects and/or an attenuated increase in activation of effort-related areas.

Study design

The study comprises two sessions lasting approximately two hours. The first session takes place at the department of neuroscience. Subjects perform 3 motor tasks during which they have to produce force with their index fingers (FDI muscle). The ulnar nerve is activated using electrical stimulation to determine the muscle activation.

The second session takes place at the neuroimaging center to repeat the motor tasks in the MR-scanner. Changes in cortical activation during the tasks are measured using a 3T MR-scanner. Muscle force is measured using MR-compatible force transducers, and muscle activation is measured by stimulating the ulnar nerve with MR-compatible surface electrodes.

During the study, subjects are asked to fill out six questionnaires*. For the serum levels of proinflammatory cytokines, data from a cohort study will be used and no additional material

needs to be collected from pSS patients.

* Fatigue: Fatigue Severity Scale, Modified Fatigue Impact Scale, Multidimensional Fatigue Inventory. Mood: Hospital Anxiety and Depression Scale. Disease activity: EULAR Sjögren's Syndrome Patient Reported Index, patient acceptable symptom state.

Intervention

Fatigue protocol

Contacts

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Eligibility criteria

Inclusion criteria

Both patients and control subjects:

- Age: 18-65 years

- Adequate hand function that allows subjects to utilize the force transducer

Patients:

- Diagnosed with pSS according to AECG and/or ACR-EULAR classification criteria

Exclusion criteria

Both patients and control subjects:

- Drug or alcohol addicition

- Neurologic condition unrelated to pSS

- Psychiatric disorder

- Other condition influencing fatigue

- Medication influencing fatigue or the immune system

- fMRI related exclusion criteria

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	15-09-2016
Enrollment:	50

Type:	Anticipated

Ethics review

Positive opinion Date:	08-09-2016
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	NL5896
NTR-old	NTR6084
Other	METc UMCG : 2016/173

Study results