Fatigue in patients with primary Sjogren’s syndrome

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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...

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Observationeel onderzoek, zonder invasieve metingen

Samenvatting

ID

NL-OMON24290

Bron
NTR

Aandoening

Primary Sjögren's syndrome (pSS)
Fatigue
fMRI
Cytokines

Primaire syndroom van Sjögren
Vermoeidheid
fMRI
Cytokines

Ondersteuning

Primaire sponsor: University Medical Center Groningen
Overige ondersteuning: University Medical Center Groningen (sponsor)

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

- 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).

Toelichting onderzoek

Doel van het onderzoek

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.

Onderzoeksopzet

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.

Onderzoeksproduct en/of interventie

Fatigue protocol

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

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

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

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

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders
Blindering:	Open / niet geblindeerd
Controle:	N.v.t. / onbekend

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	15-09-2016

Aantal proefpersonen:	50
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	08-09-2016
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

Geen registraties gevonden.

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL5896
NTR-old	NTR6084
Ander register	METc UMCG : 2016/173

Resultaten