Quantification of pain in patients with myotonic dystrophy type 2 and fibromyalgia

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1. What is the somatosensory profile of DM2 patients? 2. What are the similarities and differences between the somatosensory profile of pain in myotonic dystrophy type 2 and fibromyalgia patients?

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

Samenvatting

ID

NL-OMON22162

Bron
Nationaal Trial Register

Aandoening

Myotonic dystrophy type 2 is a rare autosomal dominant multisystem disorder. Core features are proximal weakness, myotonia, pain and cataracts.
Fibromyalgia is a highly prevalent chronic pain syndrome.
The description of pain in both disorders seem to share many similarities.

Ondersteuning

Primaire sponsor: Canisius Wilhelmina Hospital Nijmegen
Overige ondersteuning: Fonds Nutsohra

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

Somatosensory profile of pain in DM2 patients

Sample size calculation: as this is an observational study, we did not do a sample size calculation. We invite all known DM2 patients in the Netherlands, hopefully 30 of them are willing to participate. The same number of sex and age matched fibromyalgia patients and healthy controls are invited

Toelichting onderzoek

Achtergrond van het onderzoek

Rationale: Myotonic dystrophy type 2 (DM2) is a dominantly inherited multisystemic disorder with a heterogeneous phenotype. Widespread pain is an early and important symptom, for up to a third of patients the most disabling feature. The pathophysiology of pain in DM2 is largely unknown. So far, no trials have been performed to investigate the effect of treatment in DM2. There seems to be a remarkable overlap in the experienced pain in DM2 and fibromyalgia, a common syndrome with widespread pain and stiffness.

Objective: The goal of this study is to characterize and quantify pain in DM2, by accomplishing quantitative sensory testing as well as questionnaires. We expect this will lead to a better understanding of the pathophysiological nature of pain in DM2 and eventually lead to a mechanism based treatment. Furthermore, the same tests will be performed in patients with fibromyalgia. Clinically, both diseases show remarkable similarities in experienced pain. We wonder whether the somatosensory profile of pain is similar in both patient groups. If similarities in the nature of pain in both patient groups are found, treatment strategies of fibromyalgia might be used in DM2 as well.

Study design: Observational cohort study.

Study population: All known Dutch genetically proven adult DM2 patients (54) will be invited for this study. Furthermore, the same size of fibromyalgia patients in who DM2 is genetically excluded and the same size of healthy controls, both age and sex matched, will be invited as well.

Intervention (if applicable): All subjects are asked to fill in five questionnaires (McGill Pain Questionnaire, SF-36 Health Status, Pain Catastrofying Score, Pain Sensitivity Questionnaire and the Hospital Anxiety and Depression Score) and Quantitative Sensory Testing will be performed to quantify pain processing.

Main study parameters/endpoints: The main study parameter is the somatosensory profile of DM2 patients. The second parameter are the similarities and differences of the character of pain in DM2 and fibromyalgia.

Nature and extent of the burden and risks associated with participation, benefit and group

relatedness: All patients are asked to fill in five questionnaires and to visit the outpatient department once for QST testing. QST testing is harmless, but may be experienced as unpleasant. There is no immediate benefit for the patients. However, this study will give a better understanding of the pathophysiology of pain in DM2, which eventually will lead to a more directed symptomatic therapy.

Doel van het onderzoek

1. What is the somatosensory profile of DM2 patients?

2. What are the similarities and differences between the somatosensory profile of pain in myotonic dystrophy type 2 and fibromyalgia patients?

Onderzoeksopzet

Begin of 2013: writing protocol, approval of CMO region Arnhem-Nijmegen

15-08-2013: inclusion first patient

01-01-2015: ending inclusion of patients and closing database (castor)

First months 2015: analysis of data and writing scientific article

Onderzoeksproduct en/of interventie

4 questionnaires:

• McGill Pain questionnaire

• SF-36 Health survey

• Patient Catastrofying Score

• Hospital Anxiety and Depression
Quantitative Sensory Testing, including
mechanical QST, electrical QST and calculation of CPM, conditioned pain modulation.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

Three groups of patients:

1. Patients with genetically proven myotonic dystrophy type 2 (DM2)

2. Patients with fibromyalgia, matched for age and sex with DM2

3. Healthy controls, matched for age and sex with DM2

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Age younger than 18 years

- Severe illness (apart from DM2 or fibromyalgia)

- Major depression

- Moderate to severe neuropathy

- Recent (< 6 weeks) major surgery

Onderzoeksopzet

Opzet

Type:	Observationeel onderzoek, zonder invasieve metingen
Onderzoeksmodel:	Anders

Controle: N.v.t. / onbekend

Deelname

Nederland

Status:	Werving gestart
(Verwachte) startdatum:	15-08-2013
Aantal proefpersonen:	90
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	28-10-2014
Soort:	Eerste indiening

Registraties

Opgevolgd door onderstaande (mogelijk meer actuele) registratie

ID: 38498
Bron: ToetsingOnline
Titel:

Andere (mogelijk minder actuele) registraties in dit register

Geen registraties gevonden.

In overige registers

Register	ID
NTR-new	NL4719
NTR-old	NTR4864
CCMO	NL43167.091.13
OMON	NL-OMON38498

Resultaten

Samenvatting resultaten
Not yet