Gastrointestinal symptoms in myotonic dystrophic type 2 patients

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To objective the frequency and the severity of gastrointestinal dysfunction in Myotonic Dystrophy type 2 patients.

Ethical review	Approved WMO
Status	Pending
Health condition type	Gastrointestinal motility and defaecation conditions
Study type	Observational invasive

Summary

ID

NL-OMON30710

Source
ToetsingOnline

Brief title
Gastrointestinal symptoms in myotonic dystrophic type 2 patients

Condition

- Gastrointestinal motility and defaecation conditions
- Muscle disorders

Synonym
multisystem disease, Proximal myotonic myopathy (PROMM)

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Sint Radboud
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: gastrointestinal tract, Myotonic Dystrophy type 2, PROMM (proximal myotonic myopathy)

Outcome measures

Primary outcome

results of X-boz, the amount of merkers and their localization will be

counted.

results of bloodtest

result of speech therapy

Secondary outcome

niet van toepassing

Study description

Background summary

Myotonic Dystrophy type 2 (MD2) is a multisystem disease, described in 1994 as Proximal Myotonic Myopathy (PROMM) (Ricker 1994). In 2001 the genetic defect on chromosoom 3q21 was discovered (Liquori 2001). Like Myotonic Dystrophy type 1 (MD1), symptoms are progressive weakness, myotonia, cataracts en cardiac arrithmia, and the inheritance is autosomal dominant (Moxley 1998). Gastrointestinal dysfunction in MD1 has been described, and are common. In daily clinic many MD2 patients mention gastrointestinal symptoms, which were analysed by a questionairy. The results show indeed pyrosis, (60%), dysphagia (32% fluid -, and 39% non- fluid food), abdominal pain (57%) en constipation(62%) (ad 1: vragenlijst maag- en darmklachten). Gastro-intestinal symptoms in MD2 are not described in literature, and earlier findings give rise to new research in this field.

Study objective

To objective the frequency and the severity of gastrointestinal dysfunction in Myotonic Dystrophy type 2 patients.

Study design

All 27 MD2 patients who completed the questionary (bijlage 1) will be called by telephone; to get informed about this project, and they will be asked to participate. When they agree, information will be send to them (bijlage 3); a week later they will be called again for participation. The study consists of a venapunction, colon transit time measurement, and consultation by a speech therapist, and will be planned on one single day. Patients will come to hospital; after a short intake the three studies named above will take place.

Study burden and risks

The measurement of the colon transit time will be completed by X-abdomen; exposure to radiation is low. If clinical symptoms demand extra research and therapy will take place. The same day patients will be informed about the results of the studies.
Complications of a venapunction can be: hematoma, bleeding, infection, dizziness and an accidental arterial punction.
A consultion by a speech therapist has no risks; FEES-technique (Flexible Endoscopic Evaluation of Swallowing) is minimal invasive. If necessary, patients will be treated and get advices by the therapist.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

patients with Myotonic Dystrofy type 2, DNA proven on chromosome 3q21.

Exclusion criteria

pregnancy
use of medication that has influence on colonmotility during measurement of colon transittime
hypothyreoidy and depression

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-02-2007
Enrollment:	25
Type:	Anticipated

Ethics review

Approved WMO
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	NL16311.091.07