

Myotonic Dystrophy, PrOteiN and Diet study

Gepubliceerd: 23-10-2018 Laatste bijgewerkt: 18-08-2022

We hypothesize that DM1 is accompanied by impairments in whole-body and/or muscle metabolism.

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

Samenvatting

ID

NL-OMON25314

Bron

Nationaal Trial Register

Verkorte titel

MD-POuND

Aandoening

myotonic dystrophy type 1, neuromuscular disease, metabolism, body composition

Ondersteuning

Primaire sponsor: Academisch Ziekenhuis Maastricht

Overige ondersteuning: Prinses Beatrix Spierfonds

Postbus 85810

2508 CM Den Haag

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

The main study endpoints are:

- total energy expenditure measured by DLW and respiration chamber;

- resting metabolic rate (RMR) measured by respiration chamber;

- substrate selection at rest measured by respiration chamber.

Toelichting onderzoek

Achtergrond van het onderzoek

Myotonic dystrophy type 1 (DM1) is an autosomal dominant disorder that affects the skeletal, cardiac, and smooth musculature and many other tissues. While muscle weakness and myotonia (inability to relax muscles) are the main characteristics of disease, patients with DM1 frequently experience marked loss of muscle, as well as issues regarding nutrition and weight. This prospective study aims to assess metabolism in 15 patients with DM1, taking into account muscle mass, and compared to 15 healthy age-, BMI- and gender-matched subjects. We hypothesize that DM1 is accompanied by impairments in whole-body and/or muscle metabolism.

Doel van het onderzoek

We hypothesize that DM1 is accompanied by impairments in whole-body and/or muscle metabolism.

Onderzoeksopzet

total duration of 2 years

Onderzoeksproduct en/of interventie

none

Contactpersonen

Publiek

Wetenschappelijk

Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

- Age 18 years or older.
- Legally competent adult.
- Defined DM1 of the adult subtype.
- Participants must be able to walk and to cycle (in order to perform exercise tests).
- Participants must give informed consent by signing and dating an informed consent form.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

- Implantation of pacemaker or ICD device, a implantable insulin device, a neurostimulator, internal hearing aid or artificial heart valve.
- Implantation of orthopaedic prostheses, screws or plates.
- Metal shreds or splinters inside the body.
- Vascular clips in the body.
- Big tattoo's and/or permanent make-up.
- Claustrophobia.
- Use of medication interacting with muscle metabolism (such as steroids and statins).
- Diabetes mellitus.
- Weight loss of more than 3 kg in the last three months.
- Pregnant or lactating women.
- Use of protein supplements.
- Participation in an exercise program (for a study).

- Patients who are not able to perform basic activities of daily living such as walking, or patients who are suffering from other disabling comorbidity that seriously hamper physical exercise (e.g. heart failure, coronary artery disease, chronic obstructive pulmonary disease (COPD), orthopedic conditions).
- Body mass index (BMI) <18,5 or >35 kg/m².
- Use of oral anticoagulants.
- In case of DM1 affected subjects: muscular impairment rating scale (MIRS) score of 5 (which represents severe proximal muscle weakness).
- In case of the healthy control group:
presence of a neuromuscular disorder or an abnormal neurological examination (specifically if muscle weakness is present), or other condition possibly interfering with muscle strength or muscle mass

Onderzoeksopzet

Opzet

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

Deelname

Nederland	
Status:	Anders
(Verwachte) startdatum:	01-06-2018
Aantal proefpersonen:	0
Type:	Onbekend

Ethische beoordeling

Positief advies	
Datum:	23-10-2018
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	NL7374
NTR-old	NTR7582
Ander register	: METC182009

Resultaten