Physical training for children and adolescents with Juvenile Dermatomyositis.

Gepubliceerd: 07-12-2011 Laatst bijgewerkt: 18-08-2022

An individual tailored 12 weeks home-based exercise training program will increase the physical fitness, muscle strength, and quality of life, and will reduce levels of fatigue of patients with Juvenile Dermatomyositis.

Ethische beoordeling	Positief advies
Status	Werving nog niet gestart
Type aandoening	-
Onderzoekstype	Interventie onderzoek

Samenvatting

ID

NL-OMON28063

Bron
Nationaal Trial Register

Aandoening

Juvenile Dermatomyositis.

Ondersteuning

Primaire sponsor: University Medical Center Utrecht (UMCU), Wilhelmina Children’s Hospital (WKZ), Child Development and Exercise Center.
Overige ondersteuning: Nationaal reumafonds

Onderzoeksproduct en/of interventie

Uitkomstmaten

Primaire uitkomstmaten

1. Exercise capacity during a graded exercise test with respiratory gas analysis;
2. Muscle strength as assessed with hand-held dynamometry;

3. Fatigue as assessed with the PEDSQL fatigue scale.

Toelichting onderzoek

Achtergrond van het onderzoek

Aim of this intervention study is to determine the effects of an individual tailored 12 weeks home-based exercise program on the aerobic fitness and muscle strength of patients with Juvenile Dermatomyositis. Furthermore, the wash-out effects of the intervention program after another 12 weeks will be determined. Thirty children with Juvenile Dermatomyositis between 8 and 18 years will be randomly assigned in two groups (RCT). Children allocated to the intervention group will receive the exercise program. Children in the control group will only receive usual care during these 12 weeks, hereafter they also will receive the exercise program.

Doel van het onderzoek

An individual tailored 12 weeks home-based exercise training program will increase the physical fitness, muscle strength, and quality of life, and will reduce levels of fatigue of patients with Juvenile Dermatomyositis.

Onderzoeksopzet

Intervention group:

1. Measurement 1: 12 weeks training;

2. Measurement 2: 12 weeks usual care;

3. Measurement 3.

Control group:

1. Measurement 1: 12 weeks usual care;

2. Measurement 2: 12 weeks training;

3. Measurement 3: 12 weeks usual care;

4. Measurement 4.

Onderzoeksproduct en/of interventie

Treadmill training and strength training, minimal twice a week at home (30-60 minutes per session), for 12 weeks. The control group also enters the training arm directly after completing the initial protocol.

Contactpersonen

Publiek

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Wetenschappelijk

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Deelname eisen

Belangrijkste voorwaarden om deel te mogen nemen (Inclusiecriteria)

1. Diagnosed Juvenile Dermatomyositis by a pediatric rheumatologist using the Bohan and Peter criteria;

2. Be able to follow instructions regarding testing and training;

3. Parental and child informed consent;

4. Age between 8-18 years of age.

Belangrijkste redenen om niet deel te kunnen nemen (Exclusiecriteria)

1. Insufficient understanding of the Dutch language in both children and parents;

2. Medical events that might intervene with the outcome of testing;

3. Medical status that will not allow maximal exercise testing (e.g. acute fever, heart conditions).

Onderzoeksopzet

Opzet

Type:	Interventie onderzoek
Onderzoeksmodel:	Parallel
Toewijzing:	Gerandomiseerd
Blindering:	Enkelblind
Controle:	Geneesmiddel

Deelname

Nederland

Status:	Werving nog niet gestart
(Verwachte) startdatum:	01-01-2012
Aantal proefpersonen:	30
Type:	Verwachte startdatum

Ethische beoordeling

Positief advies

Datum:	07-12-2011
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	NL3036
NTR-old	NTR3184
Ander register	METC University Medical Center Utrecht (UMCU). : 11-336
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Resultaten

Samenvatting resultaten
N/A