Physical training for children and adolescents with Juvenile Dermatomyositis.

No registrations found.

Ethical review	Positive opinion
Status	Pending
Health condition type	-
Study type	Interventional

Summary

ID

NL-OMON28063

Source
Nationaal Trial Register

Health condition

Juvenile Dermatomyositis.

Sponsors and support

Primary sponsor: University Medical Center Utrecht (UMCU), Wilhelmina Children’s Hospital (WKZ), Child Development and Exercise Center.
Source(s) of monetary or material Support: Nationaal reumafonds

Intervention

Outcome measures

Primary outcome

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.

Secondary outcome

1. Muscle soreness as assessed with the 10 cm Visual Analogue Scale;

2. Muscle function as assessed with the Childhood Myositis Assessment Scale (CMAS);

3. Walking distance at the 6-minutes walking test;

4. Quality of life as assessed with the PEDSQL questionnaire;

5. Functional ability as assessed with the Childhood Health Assessment Questionnaire;

6. Physical activity as assessed by 7 days activity monitoring using an Actical accelerometer;

7. Physical activity enjoyment as assessed with the Physical Activity Enjoyment Scale.

Study description

Background summary

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.

Study objective

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.

Study design

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.

Intervention

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.

Contacts

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Eligibility criteria

Inclusion criteria

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.

Exclusion criteria

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).

Study design

Design

Study type:	Interventional
Intervention model:	Parallel
Allocation:	Randomized controlled trial
Masking:	Single blinded (masking used)
Control:	Active

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-01-2012
Enrollment:	30
Type:	Anticipated

Ethics review

Positive opinion

Date:	07-12-2011
Application type:	First submission

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
NTR-new	NL3036
NTR-old	NTR3184
Other	METC University Medical Center Utrecht (UMCU). : 11-336
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A