Muscles in Motion: Exercise rehabilitation for children and adolescents with Juvenile Dermatomyositis

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Autoimmune disorders
Study type	Interventional

Summary

ID

NL-OMON39178

Source
ToetsingOnline

Brief title
Physical training for children and adolescents with JDM

Condition

- Autoimmune disorders

Synonym
Juvenile dermatomyositis

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht

Source(s) of monetary or material Support: Reumafonds

Intervention

Keyword: Children/ adolescents, Exercise, Juvenile Dermatomyositis, Training

Outcome measures

Primary outcome

The main study parameters are:

• Exercise capacity during a graded exercise test with respiratory gas analysis

• Muscle strength as assessed with hand-held dynamometry

• Fatigue as assessed with the PEDSQL fatigue scale

Secondary outcome

• Muscle soreness as assessed with the 10 cm Visual Analogue Scale

• Muscle function as assessed with the Childhood Myositis Assessment Scale (CMAS)

• Walking distance at the 6-minutes walking test

• Quality of life as assessed with the PEDSQL questionnaire

• Functional ability as assessed with the Childhood Health Assessment Questionnaire

• Physical activity as assessed by 7 days activity monitoring using an Actical accelerometer

• Physical activity enjoyment as assessed with the Physical Activity Enjoyment Scale

• Muscle strength as assessed with the Bruininks-Oseretsky Test of Motor Proficiency 2 Subscale 8 - Strength

Study description

Background summary

Juvenile Dermatomyositis (JDM) is an auto-immune disease in which the capillaries in the muscle and skin are inflamed. Patients with JDM have significantly reduced muscle strength and exercise tolerance; even when the disease comes into remission. There is a lack of evidence to support the role of exercise as a therapy in children with JDM. Definitive evidence regarding the role of exercise in the treatment of childhood myositis is needed. Evidence from studies of adults with DM and PM and preliminary studies in juvenile arthritis and JDM provide initial evidence to suggest that exercise may be beneficial to the health outcome of childhood myositis and that exercise might be safe in this population. Therefore, exercise training may be used as a therapy to improve physical function and fitness and reduce disability in JDM. The hypothesis of this study is that an individual tailored exercise training program will increase the physical fitness (VO2peak), muscle strength, and will reduce levels of fatigue of patients with JDM.

Study objective

In this study, we want to investigate the effects of a 12 weeks home-based exercise program (treadmill trained and strengthening) aimed to improve the aerobic fitness and muscle strength of patients with JDM. Furthermore, we want to investigate the wash-out effects of this intervention program after another 12 weeks.

Study design

The study is a Randomized Controlled Trial (RCT), with the control group also entering the training arm directly after completing the initial protocol. The observers, which assess the outcome variables, will be blinded to treatment allocation.

Intervention

All children (randomly) allocated to the intervention group will receive an individual-tailored graded training program, based upon the results of the cardiovascular exercise test at baseline (t=0). The categorization of a training session will always start with 5-8 minutes warming-up, followed by a session strengthening training (sets differ each 4 weeks), hereafter aerobic training (incremental over the 12 weeks) on a treadmill, and finishing with a cooling-down of 5-8 minutes. Patients in the control group will only receive usual care during these first 12 weeks, hereafter the control group also will

receive an individual-tailored training program for 12 weeks.

Study burden and risks

Extent of the burden: The patients have to participate in a home-based aerobic and strengthening training program minimally 2 times per week, 40-60 minutes per training for 12 weeks. Furthermore, the above mentioned tests will be performed at 3 (intervention group) or 4 (control group) time points.
Risks: From the existing literature, exercise training is safe in adult patients with active as well as inactive stable idiopathic inflammatory myositis. Only one study described the effects of exercise training in a child patient with dermatomyositis [1]. In this child, no increments in disease activity were found. Another study showed that muscle inflammation as measured with MRI, myometry, and blood parameters did not increase immediately after and within 60 minutes of exercise training in patients with active and inactive JDM [2].
Benefit Evidence from studies of adults with Dermatomyositis (DM) and Polymyositis (PM) and preliminary studies in Juvenile Arthritis and JDM provide initial evidence to suggest that exercise may be beneficial to the health outcome of childhood myositis. It is hypothesized that an individual tailored exercise training program will increase the physical fitness, muscle strength, and quality of life, and will reduce levels of fatigue of patients with JDM.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)

Inclusion criteria

- Diagnosed Juvenile Dermatomyositis by a pediatric rheumatologist using the Bohan and Peter Criteria.
- Be able to follow instructions regarding testing
- Parental and child informed consent
- Age between 8-20 years of age

Exclusion criteria

- Insufficient understanding of the Dutch language in both children and parents
- Medical events that might intervene with the outcome of testing
- 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)

Primary purpose: Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	02-02-2012
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO Date:	05-12-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	21-02-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	01-10-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	20-12-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL37745.041.11