The application of near infrared spectroscopy during exercise and recovery in children with dermatomyositis: a pilot study.

Published: 23-02-2011
Last updated: 03-05-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Autoimmune disorders
Study type	Observational non invasive

Summary

ID

NL-OMON34183

Source
ToetsingOnline

Brief title
Near infrared spectroscopy in juvenile dermatomyositis.

Condition

- Autoimmune disorders
- Muscle disorders
- Vascular disorders NEC

Synonym
'Juvenile dermatomyositis'

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Exercise, Juvenile dermatomyositis, Near infrared spectroscopy, Recovery

Outcome measures

Primary outcome

The following main study parameters will be continuously determined with NIRS

in the VM and VL muscle of the dominant leg:

- Change in concentration deoxygenated hemoglobin (µM)

- Change in concentration oxygenated hemoglobin (µM)

- Change in concentration total hemoglobin (µM)

- Change in concentration deoxygenated hemoglobin minus change in concentration

oxygenated hemoglobin (µM)

The following study parameters are sole values that will be determined from the

CPET:

- Relative peak oxygen consumption as percentage of predicted (%)

- Ventilatory anaerobic threshold as percentage of predicted relative peak

oxygen consumption (%)

- Peak power output as percentage of predicted (%)

- Oxygen uptake to work rate slope (ml O2 /Watt)

The T1/2 (s) will be determined from the change in oxygenated hemoglobin

concentration data from the VM and VL muscle of the dominant leg in the

recovery phase.

Secondary outcome

Not applicable.

Study description

Background summary

Juvenile dermatomyositis (JDM) is an idiopathic chronic auto-immune disease in childhood in which the microvasculature of the skin and skeletal muscles is targeted by the immune system. This results in reduced exercise tolerance due to abnormally thickened endothelial walls of the intermuscular capillaries, arterioles, and veins, decreased capillary bed volume, and impaired perfusion in muscles (1-7).
For the assessment of the clinical course of the disease and for the evaluation of the effects of interventions and therapies, it is important to have an objective longitudinal perspective. Since the cause of the exercise intolerance in JDM is thought to be situated in the microvasculature of muscle tissue, near infrared spectroscopy (NIRS) could be a possible tool for this need. In previous studies, it was shown that it is possible to detect with NIRS abnormal muscle oxygenation patterns during exercise and recovery in patients with different levels of exercise intolerance (8). However, the application of NIRS during exercise and recovery in the study of children with dermatomyositis is not determined at present.
In the proposed pilot study, NIRS measurements will be combined with a cardiopulmonary exercise test (CPET) on a cycle ergometer. NIRS measurements will be done on the vastus medialis (VM) and vastus lateralis (VL) muscle during a single test. The data of patients with JDM will be compared with those of age- and gender matched patients with juvenile idiopathic arthritis (JIA) and healthy children.

Study objective

The objective of this pilot study is to provide information about the usefulness of NIRS in the study of patients with JDM in the test configuration as described in the protocol. For this purpose, the microvascular oxygenation and hemodynamics in thigh muscle of patients with JDM and subjects in the control groups will be qualitatively assessed during rest, incremental

exercise, and recovery with continuous wave NIRS. In this way, abnormal features could be observed. Furthermore, the microvascular function of the muscle will be quantitatively assessed by calculation of the half-recovery time of deoxygenated hemoglobin (T1/2) during recovery. This parameter is related to microvascular function. These values will be compared with those of patients with JIA and healthy subjects.
Since it is thought that patients with JDM have impaired perfusion in muscle tissue, it is hypothesised that patients with JDM show a higher T1/2. Moreover, the T1/2 values will be linked with other measures obtained during the CPET. Finally, microvascular oxygenation response data obtained from the VM and VL muscle will be compared to each other. Together, these examinations provide information about the usefulness of NIRS in the study of patients with JDM in the test configuration as described in the protocol.

Study design

In this cross-sectional pilot study, thigh muscles of a heterogeneous population of patients with JDM, patients with JIA, and healthy young subjects will be measured during rest, incremental cycling exercise, and recovery with NIRS.

Study burden and risks

For the healthy children, the load is performing a CPET with NIRS measurements once only. This test produces interesting results for the children and their parents. The risks for a CPET are minimal and NIRS measurements are safe as well. For the patient population, the only additional load is the measurement done with NIRS.
Children show different physiological responses to exercise compared to adults. Furthermore, the pathophysiology of dermatomyositis shows differences between children and adults. For these reasons, it is important to consider adult and juvenile dermatomyositis separately when studying the application of NIRS during exercise and recovery in dermatomyositis.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Children (2-11 years)

Inclusion criteria

Juvenile dermatomyositis patients: diagnose juvenile dermatomyositis; age between 8 and 18 years; informed consent signature by (the children and) the parents/caregivers.
Juvenile idiopathic arthritis patients: diagnose juvenile idiopathic arthritis; age between 8 and 18 years; informed consent signature by (the children and) the parents/caregivers.
Healthy control subjects: healthy; age between 8 and 18 years; informed consent signature by (the children and) the parents/caregivers.

Exclusion criteria

Juvenile dermatomyositis patients:
Diagnose polymyositis or myositis
Age < 8 years >= 18 years
Medical status that will not allow exercise testing
Insufficient understanding of the Dutch language in both children and parents/caregivers
No informed consent;Juvenile idiopathic arthritis patients:
Age < 8 years >= 18 years
Medical status that will not allow exercise testing
Insufficient understanding of the Dutch language in both children and parents/caregivers
No informed consent;Healthy control subjects:
Age < 8 years >= 18 years
Muscle disease in history
Chronic medication intake

Underlying auto-immune diseases
Medical status that will not allow exercise testing
Insufficient understanding of the Dutch language in both children and parents/caregivers
No informed consent

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-03-2011
Enrollment:	30
Type:	Actual

Ethics review

Approved WMO

Date:	23-02-2011
Application type:	First submission
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	NL34189.041.10