SubMaximal exercise testing to assess the AnaeRobic Threshold in nEuromusculaR diseases

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Objectives:(1) To determine whether the AT can be identified in individuals with slowly progressive NMD through submaximal exercise testing with respiratory gas analysis. (2) To determine the reliability of the AT assessment in individuals with...

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

Summary

ID

NL-OMON49622

Source
ToetsingOnline

Brief title
SMARTER

Condition

- Muscle disorders
- Neuromuscular disorders

Synonym
Neuromuscular diseases, NMD

Research involving
Human

Sponsors and support

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

Intervention

Keyword: Anaerobic threshold, Exercise testing, Neuromuscular diseases, Rehabilitation

Outcome measures

Primary outcome

The study parameters are the anaerobic threshold, heart rate, Rating of

Perceived Exertion (RPE), breathing frequency and blood pressure.

Secondary outcome

Nvt

Study description

Background summary

A primary goal of rehabilitation programs in individuals with neuromuscular diseases (NMD) is to promote physical fitness to break the vicious cycle of inactivity that they often encounter. At present, clear guidelines to individually prescribe, monitor and evaluate aerobic training programs are lacking, hampering effective application in neuromuscular rehabilitation.

The anaerobic threshold (AT), a submaximal direct marker of aerobic fitness, is used for exercise intensity prescription in the healthy population and other chronic diseases, and may also be useful in NMD. The AT is used as an intensity target which distinguishes between low- and high intensity exercise zones, enabling individuals to exercise in tailored heart rate zones. It is shown that it is possible to determine the AT through submaximal exercise testing in individuals with post-polio syndrome (a slowly progressive NMD), making it a promising tool for use in daily clinical practice. However, the reliability of this assessment within post-polio syndrome is unknown, and it is not yet determined if the AT can also be identified through submaximal exercise testing in other slowly progressive NMDs.

A major disadvantage of conventional assessment of the AT is that it is a complex and lengthy procedure requiring expensive respiratory gas analysis equipment, and is not readily available in all healthcare settings. Therefore, the next innovative step is to develop a predictive model to easily determine the AT in NMD, i.e. without the use of expensive gas analysis equipment.

Proposed methods for indirect determination of the AT are based on responses during exercise of heart rate, respiration, RPE, arterial oxyhemoglobin saturation and a combination of heart rate and blood pressure. However, these methods are mostly examined in other populations than NMD. Moreover, using a combination of these methods might increase the accuracy of the AT assessment.

Study objective

Objectives:

(1) To determine whether the AT can be identified in individuals with slowly progressive NMD through submaximal exercise testing with respiratory gas analysis.

(2) To determine the reliability of the AT assessment in individuals with slowly progressive NMD through submaximal exercise testing with respiratory gas analysis.

(3) To develop a predictive model using easy to measure variables to indirectly assess the AT through submaximal exercise testing without respiratory gas analysis in individuals with slowly progressive NMD.

Study design

A cross sectional study will be conducted at the Department of Rehabilitation of the Amsterdam UMC, location AMC.

Participants will complete three testing days. On the first and second testing day, two submaximal exercise tests will be performed, one with and one without respiratory gas analysis. On the third testing day, a maximal exercise test will be executed. Testing days will be separated by a minimum of three days.

Study burden and risks

All patients will be asked to visit the study center on 3 separate days. A total of 5 exercise tests will be performed during these visits. During the first and second testing day, two submaximal exercise tests will be performed, with 60 minutes of rest in between tests. During the third testing day, a maximal exercise test will be performed. These visits will take approximately 2 hours per visit.

To check for contra-indications for physical exercise, a physician will thoroughly examine the participants according to the guidelines by the American College of Sports Medicine (ACSM). The Amsterdam UMC, location AMC, is experienced in conducting exercise tests in patients with different neuromuscular diseases. Therefore, the occurrence of medical events is

considered minimal.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

(1) Presence of slowly progressive NMD.
(2) Ability to perform a maximal exercise test on an arm or bicycle ergometer.
(3) Minimum age of 18 years.

Exclusion criteria

(1) Absolute contraindication for exercise (based on the guidelines by the

American College of Sports Medicine)
(2) Unable to follow verbal or written instructions.
(3) Insufficient mastery of the Dutch or English language.

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Treatment

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	14-07-2021
Enrollment:	50
Type:	Actual

Ethics review

Approved WMO

Date:	08-12-2020
Application type:	First submission
Review commission:	METC Amsterdam UMC

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	NL75019.018.20