Early observational study for non-invasive measurements of exercise-induced fatigue in adult men - Exploration of candidate sensors

Published: 15-06-2020
Last updated: 08-04-2024

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Other condition
Study type	Observational invasive

Summary

ID

NL-OMON49724

Source
ToetsingOnline

Brief title
Non-invasive fatigue measurements

Condition

- Other condition

Synonym
Exercise related muscle acidification

Health condition

Geen aandoening: gezonde sportfysiologie.

Research involving

Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Ares Analytics B.V.,Financiering door Ares Analytics B.V. dmv subsidie van Metropool Regio Eindhoven

Intervention

Keyword: Breath gas analysis, Exercise test, Fatigue, Lactic acid

Outcome measures

Primary outcome

The main study parameter is the agreement between the values of candidate sensors and the actual values of the golden standards for determining exercise intensity, being lactate concentration (LA) in blood and oxygen consumption (VO2) from breath gas analysis.

In the process of creating an algorithm, it will be determined what (combination of) candidate measurements are significantly correlated to LA and VO2.

Secondary outcome

Not applicable

Study description

Background summary

Exercising at the proper intensity is important because intensities too low decrease the effectiveness of training and intensities too high increase the risk of overtraining and injuries. Currently, athletes are guided by heart rate sensors; although these heart sensors can measure the heart rate accurately, the heart rate itself is a poor indicator for the intensity of a training for an individual. Ideally, one would use the golden standards within exercise

physiology, blood lactic acid and breath gas analysis (BGA), to determine the ideal exercise intensity. These measurements, however, are burdensome to perform, require specialized expertise, and are costly.
In the literature several non-invasive and continuous parameters have shown a correlation with BGA and/or lactic acid measurements. Ares Analytics believes that by combining multiple sensors/parameters in one system, the correlation or agreement with the values of the gold standard techniques can be improved.
In this study, participants will perform three different exercise test on a bicycle ergometer. During the test the golden standards BGA and lactic acid will be measured in parallel with a set of candidate sensors to investigate the relation and develop an algorithm.
The study serves as the first step for Ares Analytics to develop a future wearable that can provide information on BGA and lactic acid measurements based on continuous, non-invasive measurements during physical exercise in healthy subjects.

Study objective

The primary objective of this study is to determine which candidate sensors alone or in combination are most correlated with the results from the gold standard technique breath gas analysis and blood lactic acid; and to develop an algorithm that leads to a close agreement between the values by these candidate sensors and the actual values measured by these golden standards.

Study design

The present study is designed as a single-center cross-sectional study in three groups of healthy, adult men. There will be three subject groups with nine participants per group; athletic with low BMI, athletic with high BMI, and non-athletic with low BMI. Each subject will be asked to perform three different exercise tests in total while various measurements are performed. The study is performed within the facilities of the department of Rehabilitation & Sports medicine at the University Medical Center Utrecht with specialized investigators.

Study burden and risks

Healthy, adult men will visit the UMCU three times over a period of two to four weeks. Each visit will take approximately one hour and includes an exhausting exercise on the ergometer bicycle. All activities are closely monitored by a sports physician and prior to the first exercise the potential health risks will be evaluated based on a standardized questionnaire and examination. During the exercise the subject will wear a mask for breath analysis and he will wear a number of non-invasive sensors (both for safety (e.g. ECG on the chest) and the candidate sensors on the upper legs). In addition, per exercise test, a maximum of 22 droplets of blood will be taken from the earlobe for the lactic

acid analysis.
Subjects will be reimbursed for costs made as a results of study participation (e.g. travel and parking costs and money for the 2nd and 3rd test). In addition, the subjects will be informed of their fitness, VO2max score, including advice for their training schedules, and given general feedback about whether or not abnormalities were found with their ECG measurements.

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

Male
Age 18-40 years
18.5 < BMI < 23 or 27 < BMI < 30
Athletic or non-athletic

No physical limitation to do the exercise tests

Exclusion criteria

a. < 18 years and > 40 years
b. Women
c. Use of medication that affect the lung or circulatory system
d. (Previous) musculoskeletal injuries that could affect cycling
e. Physical limitations for cycling
f. Significant anatomical differences between dominant and non-dominant leg
g. Cardiovascular disease or abnormalities
h. Pulmonary disease or abnormalities
i. Muscle or metabolic diseases (e.g. diabetes, McArdle*s disease)
j. Significantly abnormal anatomy of the leg (e.g. due to severe muscle injuries) or
k. Abnormal skin around Vastus Lateralis (major muscle in the upper leg)
l. Potential issues lactate measurements: phobia for needles or blood, blood clotting issues

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	03-09-2020
Enrollment:	27
Type:	Actual

Ethics review

Approved WMO Date:	15-06-2020
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	25-08-2020
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	NL72884.041.20