Monitoring of training effects with gene expression patterns of athletes

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

Summary

ID

NL-OMON46884

Source ToetsingOnline

Brief title Genes On the Move / GOM

Condition

• Other condition

Synonym

mild muscle damage due to normal exercise and training

Health condition

vermogen tot herstel van lichte spierschade en adaptatie aan inspanning en training bij gezonde personen

Research involving

Human

Sponsors and support

Primary sponsor: Stichting Hogeschool Leiden **Source(s) of monetary or material Support:** SIA-RAAK

Intervention

Keyword: exercise test, gene expression, healthy athletes, RNA-profiles

Outcome measures

Primary outcome

RNA-profiles of blood cells, as indication of functional alterations in gene

expression in leukocytes.

Exercise performance parameters as described in the model by Joyner and Coyle (2008) as determined measured during the maximal incremental exercise tests at the start and end of the project: Performance VO2 - VO2max, VO2 at the ventilatory threshold, performance O2 deficit, gross efficiency, peak power output and average power output attained during a Wingate test.

Secondary outcome

The secundary objectives are:

 To assess the correlation between changes in gene expression patterns and changes in exercise performance in individuals to determine the effects of training during and after a regular training period of approximately 12 weeks.
The secondary study parameters will be the same as the primary endpoints.
To assess the correlation between changes in gene expression patterns with changes in several physiological performance-determining variables and changes in metabolites. In the model described by Joyner and Coyle (7) four main physiological parameters are considered to be important for exercise performance: 1) VO2max, 2) VO2 at the lactate or ventilatory threshold, 3) anaerobic capacity (performance O2 deficit), and 4) GE. Therefore, secondary study parameters are related to these four physiological parameters.

3) To investigate the suitability of small blood samples obtained from finger pricks for the generation of gene expression patterns.

The quality of RNA isolated from finger prick and venous blood samples will be compared. When sufficient, RNA profiles will be generated from both sources. These will be compared to determine if finger prick profiles can be used to detect similar effect sizes and adequately monitor changes in gene expression. 4) To select and test a set of differentially expressed genes for the

development of a specific test to monitor training effects.

RNA-Seq is a sensitive technique, but time-consuming and still expensive. To effectively monitor training effects, a specific test based on a subset of genes which are differentially expressed under the study conditions would be required. To develop a specific test a set of differentially expressed genes selected in the pilot study will be validated by quantitative RT-PCR in the main study.

Study description

Background summary

Athletes aim together with their coaches and trainers to achieve the best performance. Optimal adjustment of training to the individual athlete increases the chances of winning. For this, objective measurement of training effects is of great importance. In general, genes react to internal or external stimuli by becoming more active, less active or showing no response. These personal changes in gene expression can be detected in RNA-profiles. Previous studies suggest that RNA-profiles obtained from whole venous blood taken before and after physical exercise differ between non-trained and trained individuals. Presumably, changes in gene expression are correlated with adaptation to training stimuli. This study aims to monitor the acute and chronic effects of training using an exercise test combined with gene expression analysis. We hypothesize that gene expression patterns obtained from white blood cells can be used as objective measurements to assess the performance and health status of individual athletes.

Study objective

The primary objective is to assess how training, acutely and chronically, influences gene expression patterns in different individuals. Gene expression values of samples taken around an exercise performance test will be used to assess the acute effects of physical exercise. The chronic effects of regular cycling training on performance will be determined using a standardized exercise test and by gene expression levels determined at similar time points relative to the exercise performance test. The secondary objectives are: 1) to assess the correlation between changes in

gene expression patterns and exercise performance; 2) to assess the correlation between changes in between changes in gene expression patterns with physiological performance-determining variables and changes in metabolites; 3) to investigate the suitability of small blood samples obtained from finger pricks for the generation of gene expression patterns; 4) to select and test a set of differentially expressed genes for the development of a specific test to monitor training effects.

Study design

Prospective observational cohort study, in which the subjects will be subjected to a 3-month training program. The study is divided in two parts, the pilot study and the main study. In the pilot study, the feasibility of using small blood samples obtained from finger pricks for the generation of gene expression patterns will be investigated. When sufficient RNA of good quality can be obtained from finger prick samples, the main study will validate if these can replace venous blood samples. In both studies, the same intervention will be performed during a three-month period. Standardized exercise tests (45 min cycling at 60% maximal power output attained during a maximal incremental exercise test (Wmax) and 15 min time trial) will be performed before the start of the training period and at 1-month intervals over a period of 3 months. Each participant has to perform a maximal-incremental test before and after the 3-month training period to determine the Wmax.

Study burden and risks

A 3-month training schedule is offered to the subjects participating in this

study. This can result in a performance improvement and improve their general health status. In addition, measurements of the maximal voluntary oxygen consumption (VO2max) and peak power output (PPO) can be of interest for this group of trained cyclists. The risks for the subjects related to this study are minor. VO2max is determined at the start and the end of the study using a maximal incremental test, PPO is determined at the start and end of the study using a Wingate test. An exercise performance test consisting of 45 min cycling at 60% Wmax followed by a 15 min time trial has to be performed monthly during the training period. These tests will be well-tolerated by trained cyclists. There is a small risk of bruising due to the blood sampling procedures. Blood for RNA-profiles will be collected around each exercise performance test (4 tests per person, during 3 months), which means that subjects have to be in the lab for 2 h. Approximately \sim 24 h after the start of the performance test additional blood samples will be taken. Furthermore, they have to complete a 24-h diet log before the first performance test, a training log, and report illnesses/injuries during the whole study period.

Contacts

Public Stichting Hogeschool Leiden

Darwinweg 24 Leiden 2333 CR NL **Scientific** Stichting Hogeschool Leiden

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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Age

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

Inclusion criteria

- Healthy males
- -18-50 years old

- Recreationally trained track or road cyclists (VO2-max >= 45ml/kg/min), with at least two years of cycling experience of at least twice a week

- Meeting criteria of a valid maximal incremental exercise test
- Body mass index (BMI) 20-25 kg/m2
- Veins suitable for blood sampling at inspection

- Based on the outcome of the anamnesis form, participants should be rated as low risk participants

Exclusion criteria

Men with health problems and/or without sporting activity or above 50 years old

- Known diagnosis of immune disease such as diabetes, coeliac disease, rheumatoid arthritis

- Known diagnosis of gastro-intestinal disease such as Crohn*s disease, colitis ulcerosa,

irritable bowel syndrome

-Smoking

-Use of hard drugs

-Use of specific medicines:

*chronic use of NSAIDs: aspirin, ibuprofen, corticosteroids

*chronic use of antidepressiva, antacids (Rennie), benzodiazepines (Valium

* drugs against abdominal pain and cramping (e.g.buscopan, imodium),

-Participation in other scientific studies within 1 month before the preliminary testing

Study design

Design

Study type: Observational invasive

Masking:

Control:

Open (masking not used) Uncontrolled

Primary purpose:

Health services research

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	24-10-2017
Enrollment:	40
Туре:	Actual

Ethics review

Approved WMO	
Date:	08-09-2017
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl
Approved WMO	
Date:	01-12-2017
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
	metc-ldd@lumc.nl
Approved WMO	
Date:	02-07-2018
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden)
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Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

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Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register

ССМО

ID NL59983.058.17