Respiratory timing during exercise

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2.1 Primary Objective(s):The primary objective of this study is to determine whether analysis of breath-to-breath respiratory variability provides more information on the mechanism that is responsible for the RCP. Two hypotheses are tested: 1. After...

Ethical review	Approved WMO
Status	Pending
Health condition type	Respiratory disorders NEC
Study type	Observational invasive

Summary

ID

NL-OMON45264

Source
ToetsingOnline

Brief title
Respiratory timing during exercise

Condition

- Respiratory disorders NEC

Synonym
does not apply

Research involving
Human

Sponsors and support

Primary sponsor: Noordwest Ziekenhuisgroep
Source(s) of monetary or material Support: de stichting Pulmoscience;Alkmaar

Intervention

Keyword: cardiopulmonary exercise test (CPET), respiratory compensation point (RCP)

Outcome measures

Primary outcome

The primary objective of this study is to determine whether the analysis of breath-to-breath respiratory variability provide more information on the mechanism that is responsible for the RCP.

The main study parameters are the breath-to-breath variability of VT, TI and TE.

Secondary outcome

The secondary objectives of this study are to assess the RCP acting as phenomenon, and the timing of the anaerobic threshold (AT) and lactic acidosis in relationship to the RCP

Study description

Background summary

The respiratory compensation point (RCP) is the point during incremental exercise at which the ventilation suddenly increases in response to lactic acidosis. This is visible as a sudden decrease in partial pressure of carbon dioxide (pCO2) in arterial blood. It is remarkable that there is usually a delay between the onset of lactic acidosis and this respiratory response. This delay is called the *isocapnic buffering phase. The mechanism that is responsible for the RCP is unclear.
RCP is an important factor in the development of dyspnoea during exercise. Dyspnoea is the most important complaint of patients with cardiopulmonary disease. For instance, shortness of breath has a major impact on exercise capacity and quality of life in patients with chronic obstructive pulmonary disease (COPD)(3). However, in many patients the nature of ventilatory limitation during exercise is also unclear.
To shed more light on the mechanism of the ventilatory response during exercise we applied the analysis of breath-to-breath respiratory variability. In healthy subjects this type of analysis provided insights into the respiratory control system.
Analysis of breath-to-breath respiratory variability may provide more

information about the mechanism of the respiratory compensation point.
Preliminary data of a small cohort of nine healthy subjects showed that after the RCP the breath-to-breath variability of tidal volume (VT), inspiratory time (TI) and expiratory time (TE) is reduced. These data also showed that, after the RCP, TI and TE are tightly coupled.
An extension of this analysis will improve the knowledge about the regulatory mechanisms of respiration during exercise and tachypnoea as a cause of the shortness of breath that patients experience during exercise.
An incremental exercise test is a useful non-invasive diagnostic tool to assess the ventilatory mechanisms during exercise. Therefore, more knowledge about these mechanisms improves the diagnostic power of the incremental exercise test and will prevent the patient from further, more invasive diagnostic tests.
Our main objective is to improve the understanding of the respiratory compensation point during exercise. To this end we applied the analysis the breath-to-breath respiratory variability after the RCP in a group of healthy, well trained subjects during an incremental exercise test.

Study objective

2.1 Primary Objective(s):
The primary objective of this study is to determine whether analysis of breath-to-breath respiratory variability provides more information on the mechanism that is responsible for the RCP.
Two hypotheses are tested:
1. After RCP the breath-to-breath variability of VT, TI and TE is reduced.
2. After RCP there is a tight coupling between TI and TE.

2.2 Secondary Objective(s):
The secondary objectives of this study are to determine the RCP, and the timing of the anaerobic threshold (AT) and lactic acidosis in relationship to the RCP.

Study design

This study will be set up as a prospective, observational study. Eligible participants will be sought at recreational cycle clubs and approached by the investigators orally or by advertisement.
An incremental exercise test will be performed in all subjects.
This study will be conducted in the hospital of the Noordwest Ziekenhuisgroep, location Alkmaar.

Study burden and risks

The subjects will be asked for a day to be present in the North West Group Hospital, location Alkmaar. During this day there is a short history, physical examination, and the screenings tests will be performed; a venipuncture, ECG and spirometry. If a subject is found to be suitable for participation a

incremental exercise test is carried out with an radial artery puncture twice.

Risks
Venipuncture: local hematoma
Radial artery puncture: local hematoma, arterial spasm, local hematoma, fainting or a vasovagal response.
The risks are small, because the punctures are performed by experienced analysts. The damage wich could occur is reversible.

Subjects receive a report of the incremental exercise test; thus they gain insight into their overall fitness and performance

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. Healthy subject
2. Caucasian male: 18-45 years old
3. Well trained recreational cyclists
4. Written informed consent obtained.

Exclusion criteria

1. Body mass index (BMI) < 18 kgm2 or >25 kgm2
2. Known cardiopulmonary disease, or ECG or spirometrie suggestive of cardiopulmonary disease
3. Active smoking, smoking history; >5 packyears
4. Hypertension; defined as blood pressure > 140/90 mmHg (millimeters of mercury).
5. Renal failure; defines as Estimated Glomerular filtration rate (eGFR) using Modification of Diet in Renal Disease (MDRD) formula; < 60 ml/min.
6. Anaemia; defined as haemoglobin < 7.5 mmol/l

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	16-04-2017
Enrollment:	32
Type:	Anticipated

Ethics review

Approved WMO

Date:	27-06-2017
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	NL60007.094.16