RAMP
A study to investigate the difference in maximum oxygen uptake capacity during cardiopulmonary exercise testing (CPET) in healthy adult men, age 40-70 years, between ramp-protocol and standard one minute-step protocol.

Published: 14-08-2015
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Do healthy adult males, age 4-70 years without cardio- or pulmonary disease reach a higher maximum oxygen uptake at cardiopulmonary exercisetest with the ramp-protocol in comparison to the standard bloc-protocol? P: healthy adult man, age 40 en 70…

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

Summary

ID

NL-OMON42634

Source
ToetsingOnline

Brief title
RAMP

Condition

- Heart failures
- Muscle disorders
- Respiratory disorders NEC

Synonym
heart and lungfunction, maximum oxygen uptake

Research involving
Human

Sponsors and support

Primary sponsor: Diaconessenhuis Leiden
Source(s) of monetary or material Support: opdrachtgever;interne subsidieverstrekker

Intervention

Keyword: Borgscore / perceived exertion, exersise test, protocol selection, VO2 peak

Outcome measures

Primary outcome

maximum oxygen uptake,

Secondary outcome

lactate

Borgscore

Study description

Background summary

An screening file research at the Alrijne Hospital Leiden showed that in 2014 in 29% of the cardiopulmonary exercisetests the test is stopped due to fatigue in the legs, while were still cardiac and pulmonary reserves. The achieved oxygen uptake was may be not the maximum. Therefore it is possible that a patient is wrongly rejected for lobectomy.

Cardiopulmonary exercisetest is a stress test with measurement of oxygen uptake. At Alrijne Hospital Leiden the standaard protocol used is the the block protocol: a pre-established number of Watts per minute increase, this tax remains a constant, then the next minute increase follows.

At the ramp-protocol the watts increase constantly,per second, so there is no peak load on the legs, the exersise is more easy to sustain. The predicted

value is evenly divided over 10 minutes. With the current exercisesystems this can be set accurately.

Thesis: when the load is increased, but not per minute per second (disaster), there is no peak load on the leg muscles and the patient may sustain the effort any longer. The achieved VO2 can therefore be higher. The chance of curative Lobectomy is increasing.

Hypothesis:

H0: there is no significant difference in maximum oxygen uptake at the ramp-protocol

HA: there is a significant difference in maximum oxygen uptake at the ramp-protocol

Study objective

Do healthy adult males, age 4-70 years without cardio- or pulmonary disease reach a higher maximum oxygen uptake at cardiopulmonary exercisetest with the ramp-protocol in comparison to the standard bloc-protocol?

P: healthy adult man, age 40 en 70 jaar
I : Ramp-protocol
C: Blok-protocol
O: maxymum oxygen uptake

The results will determine wich protocol will be used at preoperative cardiopulmonary exercisetests in Alrijne Ziekenhuis Leiden.

If an higher oxygen uptake at rampprotocol is found in this research, an follow-up RTC research will be planned.

Study design

It is a comparising study, without longitudinal component in a cross-over design.
The group of subjecst is formed by self-selection. Subjects can respond to a recruitment ad and there will be actively recruited in the network of supervising doctor and researcher.

sample size:

It is a pilot study in order to be able to identify a possible trend in the maximum VO2 at different exercise protocol. For practical reasons, en available time, space and equipment may 25 healthy men included.

The inclusion criteria are:

• Men
• Age 40-70 years

The exclusion criteria are:

• No cardiac problems
BMI > 25 kg/m2
• No pulmonary problems
• Can not cycling on the bicycle ergometer
• Panic disorders, particularly claustrophobia

Study burden and risks

the subject starts with a consultation at the Physician assistant.
cardiopulmonary exercise test is almost without any risk for healthy persons, althoug one can feel exhausted afterwards..
incidentely, there may occur some cardial rythm problems and/or shortness of breath.

at the prickspot may occur an hematoma

subjects time spend for this research will be 120 minutes

Contacts

Public
Diaconessenhuis Leiden

Houtlaan 55
Leiden 2334 CK

NL
Scientific
Diaconessenhuis Leiden

Houtlaan 55
Leiden 2334 CK
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

healthy male adults age 40-70

Exclusion criteria

no pulmonary diseases, no cardial diseases, no panic disorder, able to cycle on ergometer, BMI > 25 kg/m2

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled

Primary purpose:	Diagnostic

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	07-09-2015
Enrollment:	25
Type:	Actual

Ethics review

Approved WMO

Date:	14-08-2015
Application type:	First submission
Review commission:	METC Leids Universitair Medisch Centrum (Leiden)

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	NL53762.058.15