High altitude simulation and weight management

Published: 23-03-2010
Last updated: 04-05-2024

The primary objective is to show that energy expenditure of the body, during moderate physical activity on a bike ergometer, can become higher in response to high altitude simulation. The secondary objetive is to show that an increase in energy...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Other condition
Study type	Interventional

Summary

ID

NL-OMON33006

Source
ToetsingOnline

Brief title
Hypoxia and weight management

Condition

- Other condition

Synonym
bulky, Corpulence

Health condition

overweight (25 < BMI < 30)

Research involving
Human

Sponsors and support

Primary sponsor: HAN University (Hogeschool van Arnhem en Nijmegen)
Source(s) of monetary or material Support: Ministerie van OC&W,Senter Novem PID07096

Intervention

Keyword: High altitude simulation, Lactate metabolism, Normobaric hypoxia, Weight management

Outcome measures

Primary outcome

As parameter of energy expenditure whole body oxygen consumption is measured via indirect calorimetry (ventilated hood).

A work load of 85 Watt on a bike ergometer (the maximum in this study) requires at sea level an energy expenditure of 20.4 kJ/min.

We expect that the same work load under high altitude simulation requires an energy expenditure of 28.6 kJ/min, an increase of about 40%.

In other words a work load of 85 Watt under high altitude simulation is associated with an energy expenditure for which under sea level conditions a work load of 115 Watt has to be applied.

Secondary outcome

The CO2 production of the subjects is also measured via the ventilated hood system. In combination with the oxygen consumption the Respiratory Quotient (RQ = CO2/O2) can be determined. Changes in RQ are indicative for for changes in substrate use. During the exercise protocols at regular time intervals 10 ul blood samples are taken from the middle finger to detect changes in glucose and lactate levels in peripheral blood. During the exercise protocols the lactate

level should be higher compared to rest and may increase slightly.

The physiological condition of the subjects is continuously monitored via

oxygen saturation of the blood (SpO2), the heart rate (HR) and a RPE (Rate of

Perceived Exertion) questionaire. The protcol is stopped when the subject wants

to do so and when the pre-determined endpoint values are reached; SpO2 < 90% en

HR > 80% HRmax.

Study description

Background summary

An unintended loss of body weight is not uncommon for mountaineers and for people otherwise exposed to high altitude conditions (thin air) for a longer period of time. COPD patients may experience similar effects because of their respiratory problems. The nature of the weight loss is not always clear and is supposed to be multifactorial. A reduction in body weight can be caused by a loss of body water, body fat or lean body mass (protein). The size of the weight loss seems to be related to the level and the duration of the high altitude exposure, to the level of physical activity at altitude as well as to the individual tolerance to high altitude conditions. Dehydration, reduced appetite, a change in metabolic substrates and an increase in energy expenditure have been suggested as potential mechanisms for weight loss under high altitude conditions. The evidence for high altitude weight loss suggests that exercise programmes for weight management could benefit from high altitude simulation at sea level. An innovative approach of exercise programmes that make use of high altitude simulation to increase energy expenditure provides in our view the best perspective voor weight management. An acute increase in energy expenditure, in response to high altitude simulation, has to be expected when lactate, produced as residual product of anaerobic glycolysis,is cleared by gluconeogenesis. It is well known that energy expenditure of the body increases upon an increase in the level of gluconeogenesis.

Study objective

The primary objective is to show that energy expenditure of the body, during moderate physical activity on a bike ergometer, can become higher in response to high altitude simulation. The secondary objetive is to show that an increase in energy expenditure can be linked to the clearance of lactate produced under

high altitude simulation as by product of as anaerobic glycolyis.

Study design

The study has a 'Randomised controlled single blind cross-over design'

Intervention

The study consists of a exercise protocol of 30 min. This exercise protocol is executed twice, once under sea level conditions and once under high altitude simulation (2000 m). For each individual the level of exercise is predetermined by means of a LSSH (Lactate steady State - Hypoxia) screening protocol.

Study burden and risks

In order to participate in the study subjects have to fill in a questionairre and will be subjected to a sport medical screening (a.o. ECG at max work load, long function test). Based on this information obtained the sports physician decides about in- or exclusion of the subjects. A LSSH (Lactate Steady State - Hypoxia) screening is used to determine the highest word load (stages of 15 Watt) under which the subject is able to maintain a constant lactate level under high altitude simulation. The exercise protocols will be performed under sea level conditions and under high altitude simulation condition at a work load 3 stages (= 45 Watt) lower. During the exercise protocols oxygen consumption will be measured by indirect calorimetry (ventilated hood). During the LSSH screening and the exercise protocols subjects have to behave s quite as possible (no talking etc). On the morning of the sport medical screening, the LSSH screening and the exercise sessions subjects have to come to the test facilcity (HAN - SENECA) in an overnight fasting condition. During the LSSH screening and the exercise session at max 12 small blood samples are taken from the middle finger. At certain time intervals subjects are asked about their 'Rate of Perceived Exertion' (RPE).

Contacts

Public
HAN University (Hogeschool van Arnhem en Nijmegen)

Verlengde Groenestraat 75
6525 EJ Nijmegen
NL
Scientific
HAN University (Hogeschool van Arnhem en Nijmegen)

Verlengde Groenestraat 75
6525 EJ Nijmegen
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Women
Self reported healthy
20 - 40 years
25 < BMI < 30
Non - smoking
Activity level < Dutch 'Fitnorm'

Exclusion criteria

Extreme sensitive to hypoxia (oxygen saturation < 90 % at pO2 = 129 mm Hg)
• Anaemia (Hb < 7.5 mmol/L, Hc < 41%)
• Diabetes (fasting plasma glucose > 5.8 mmol/L and/or glucosuria)
• Following weight-reduction programme or medically prescribed diet
• Weight change > 2 kg during the last 2 months
• Medication that may influence energy metabolism, weight or food intake
• Gastrointestinal disorders (blood in stool, constipation and diarrhoea)
• History of medical or surgical events that may affect the study outcome
• Blood donation in the last month before the study or during the study
• Abnormal ECG or impaired lung function

Study design

Design

Study type:	Interventional
Intervention model:	Crossover
Masking:	Single blinded (masking used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	01-06-2010
Enrollment:	20
Type:	Actual

Ethics review

Approved WMO

Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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	NL29211.091.09