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Influences of short-term normobaric hypoxic training on metabolic syndrome-related markers

Submission date
18/08/2017

Recruitment status
No longer recruiting

Registration date
25/08/2017

Overall study status
Completed

Last Edited
24/08/2017

Condition category
Nutritional, Metabolic, Endocrine

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Hypoxic training involves training while breathing hypoxic (low oxygen) air. Although not commonly used, hypoxic training may be beneficial for people with clinical conditions such as coronary artery (heart) disease and chronic obstructive pulmonary (lung) disease. However, the effects of hypoxic training vary greatly according to the oxygen level, exercise intensity, time and duration, and also vary considerably among individuals. The aim of this study is to examine the effects of hypoxic training on factors related to metabolic syndrome (a combination of diabetes, high blood pressure and obesity).

Who can participate?
Men aged 18 or over

What does the study involve?
Participants are divided into two groups based on their body mass index. Participants in the overweight and normal-weight groups are then randomly allocated into either the hypoxic exercise group (hypoxic overweight and hypoxic normal-weight) or the normoxic exercise group (normoxic overweight and normoxic normal-weight). Participants perform treadmill exercise three days per week for four weeks under either hypoxic (low oxygen) or normoxic (normal oxygen) conditions, for 50 minutes (including 5 minutes warm-up and cool-down periods) after a 30-minute rest period. Markers of metabolic syndrome are measured using blood sampling at the start and the end of the study.

What are the possible benefits and risks of participating?
These results may show that hypoxic training could be useful for improving arterial (blood vessel) stiffness, circulatory system function, body composition and metabolism in adult men.

Where is the study run from?
Gifu University (Japan)

When is the study starting and how long is it expected to run for?
March 2014 to May 2015

Who is funding the study?
University of Ulsan (South Korea)

Who is the main contact?
Dr Sohee Shin

Contact information

Type(s)
Public

Contact name
Dr Sohee Shin

Contact details
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44610

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
-

Study information

Scientific Title
Influences of short-term normobaric hypoxic training on metabolic syndrome-related markers in overweight and normal-weight men: a randomised controlled trial

Study objectives
Short-term normobaric hypoxic training influences metabolic syndrome-related markers in overweight and normal-weight men positively.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Institutional review board of the Gifu University School of Medicine, 06/03/2013, ref: 24-392

Study design

Interventional randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Metabolic syndrome

Interventions
Forty-one Japanese men were included and were divided into two groups based on their body mass indexes (BMIs): BMI ≥25 or BMI <25. Participants in the overweight and normal-weight groups were randomised into the hypoxic exercise group (hypoxic overweight, HO; hypoxic normal-weight, HN) or the normoxic exercise group (normoxic overweight, NO; normoxic normal-weight, NN). Subjects performed treadmill exercise three days per week for four weeks at an exercise intensity of 60% maximum heart rate (HR), under either normobaric hypoxic or normobaric normoxic conditions, for 50 min (including 5 min warm-up and cool-down periods) after a 30-min rest period. Duration of follow-up: 4 weeks.

Intervention Type
Other

Primary outcome measure
Metabolic syndrome-related markers, measured using blood sampling at baseline and 1 month

Secondary outcome measures
Body composition, measured using body composition analyzer (TANITA Co., Tokyo, Japan) at baseline and 1 month

Overall study start date
30/03/2014

Completion date
30/05/2015

Eligibility

Key inclusion criteria

1. All patients admitted to one of the participating wards
2. Aged 18 years or over
3. Able to provide informed consent to participate

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Male

Target number of participants
Planned sample size: 40: Japanese sample size: 40

Key exclusion criteria
1. Coronary heart disease
2. Cardiac insufficiency
3. Pulmonary disease
4. Uncontrolled hypertension

Date of first enrolment
30/03/2014

Date of final enrolment
30/08/2014

Locations

Countries of recruitment
Japan

Study participating centre
Gifu University
501-1194

Sponsor information

Organisation
University of Ulsan

Sponsor details
93 Daehak-ro, Nam-gu
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44610

Sponsor type
University/education

Website
http://www.ulsan.ac.kr/

ROR
https://ror.org/02c2f8975

Funder(s)

Funder type
University/education

Funder Name
University of Ulsan

Alternative Name(s)
UOU

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Korea, South

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer reviewed journal.

Intention to publish date
01/11/2017

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from Dr Sohee Shin.

IPD sharing plan summary

Available on request