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Effects of exercise training on obstructive and central sleep apnea in coronary artery disease

Submission date
15/09/2014

Recruitment status
No longer recruiting

Registration date
23/09/2014

Overall study status
Completed

Last Edited
15/10/2020

Condition category
Circulatory System

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Sleep apnea is a common sleep disorder in which breathing repeatedly stops and starts again as you sleep. There are 2 forms. Obstructive apnea (OSA) happens when the soft tissue at the back of your throat relaxes and blocks your airway. Central apnea (CSA) happens when your brain fails to stimulate your respiratory muscles to breathe. Sleep apnea prevents restful sleep and is linked with cardiovascular disease, including stroke and heart failure. The build-up of fluid in the legs during the day and then the shifting of this fluid into the neck and lungs due to gravity when in bed at night are related to OSA and CSA severity, respectively. Exercise training (ET) reduces the symptoms of sleep apnea, but we do not know why this is the case. The most likely cause, however, is the contraction of the calf muscle; this forces fluid out of the legs and reduces the amount of fluid shifting from the legs to the neck and lungs during sleep. ET in patients with coronary artery disease (CAD) reduces death rates, but again we dont know why. Sleep apnea increases the risk of death for CAD patients. Therefore, it is possible that ET could reduce the risk of death in CAD patients by reducing the severity of sleep apnea. Here, we want to see if ET does reduce OSA and CSA symptoms by reducing the amount of fluid build-up in the legs during the day and its movement into the neck and lungs at night.

Who can participate?
Adults aged between 18-80 with CAD.

What does the study involve?
Participants first undergo a sleep study to see whether they have OSA or CSA. Those that are found to suffer from sleep apnea are then randomly allocated into one of two groups. Those in group 1 do an exercise training programme for 5 days a week for 4 weeks. It includes some moderately intensive aerobic exercise and some light resistance training. Those in group 2 simply wait for a 4 week period. Physical activity levels of all the participants are measured at the start of the study using a actigraphy, an instrument worn on the wrist that measures movement of the body. All participants have the fluid content of their legs, neck and lungs measured and the severity of their sleep apnea assessed at both the beginning and end of the trial.

What are the possible benefits and risks of participating?
Participants that undergo the exercise training program may benefit from an improvement in the severity of their sleep apnea and overall improvement of their cardiovascular health.

Where is the study run from?
Toronto Rehabilitation Institute (Canada)

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

Who is funding the study?
Canadian Institutes of Health Research (Canada)

Who is the main contact?
Dr Monique Mendelson
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

Protocol serial number
N/A

Study information

Scientific Title
Effects of exercise training on obstructive and central sleep apnea in coronary artery disease: a randomized controlled trial

Study objectives
1. In coronary artery disease patients with obstructive sleep apnea, exercise training will reduce the apnea-hypopnea index in association with decreases in evening leg fluid volume, overnight changes in leg fluid volume and neck fluid volume and an increase in upper-airway cross-sectional area.
2. In coronary artery disease patients with central sleep apnea, exercise training will reduce the

apnea-hypopnea index in association with decreases in evening leg fluid volume and overnight change in leg fluid volume and change in thoracic fluid volume, and an increase in PCO2 above the apnea threshold during sleep.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University Health Network Research Ethics Board; 09/09/2014; ref. 14-7748

Study design
Single-centre randomized controlled parallel group trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Coronary artery disease patients with obstructive or central sleep apnea

Interventions
The intervention consists of an exercise training program including 20 sessions over a 4-week period. Each exercise session will begin with a 10 minute warm-up followed by 30 minutes of moderate-intensity aerobic exercise, as recommended by the American College of Sports Medicine and the Canadian Association of Cardiac Rehabilitation. Following aerobic exercise, on non-consecutive days, participants will perform approximately 20 minutes of supervised light resistance training. The intensity of aerobic exercise will be set at 60-80 % of peak oxygen uptake (VO2) or 70-80% heart rate reserve, as determined from the maximum exercise test. The control group does not receive any intervention. They simply wait for a 4-week period.

Intervention Type
Other

Phase
Not Applicable

Primary outcome(s)
Apnea hypopnea index, measured by polysomnogram at baseline and 4-weeks

Key secondary outcome(s))
1. Leg fluid volume measured by bio-electrical impendence
2. Overnight changes in leg fluid volume, thoracic fluid volume, neck circumference and neck fluid volume measured by bio-electrical impendence
3. Upper-airway cross-sectional area measured by acoustic pharyngometry

Completion date
01/09/2015

Eligibility

Key inclusion criteria
Men and women 18-80 yrs of age with coronary artery disease (defined as a documented myocardial infarction, coronary bypass surgery or coronary angioplasty and/or stenting) and obstructive or central sleep apnea (AHI greater than 15 events/hr)

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
80 years

Sex
All

Total final enrolment
34

Key exclusion criteria
1. Angina
2. Use of diuretics
3. Adeno-tonsillar hypertrophy
4. Inability to walk due to orthopedic or musculoskeletal problems
5. Previously treated OSA
6. Patients exercising more than 150 minutes per week at moderate intensity

Date of first enrolment
17/09/2014

Date of final enrolment
01/09/2015

Locations

Countries of recruitment
Canada

Study participating centre

550 University Avenue
Toronto
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Sponsor information

Organisation
Canadian Institutes of Health Research

ROR
https://ror.org/01gavpb45

Funder(s)

Funder type
Government

Funder Name
Canadian Institutes of Health Research - operating grant (MOP-82731)

Alternative Name(s)
Instituts de Recherche en Santé du Canada, Canadian Institutes of Health Research (CIHR), CIHR_IRSC, Canadian Institutes of Health Research | Ottawa ON, CIHR - Welcome to the Canadian Institutes of Health Research, CIHR, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/07/2016	15/10/2020	Yes	No
Results article	results	15/01/2020	15/10/2020	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes