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Effects of compression stockings on severity of obstructive sleep apnoea

Submission date
08/06/2012

Recruitment status
No longer recruiting

Registration date
21/06/2012

Overall study status
Completed

Last Edited
20/01/2020

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Obstructive sleep apnoea (OSA) is a common sleep-related breathing disorder, in which the throat closes repetitively, blocking the flow of air into the lungs when a person is sleeping. The usual treatment for OSA is continuous positive airway pressure (CPAP) which is a small mask that fits over the nose connected to a machine which blows air at a low pressure into the throat, preventing it from collapsing during sleep. Although it may work well, many people find it uncomfortable and cannot use it. Therefore, alternative treatments for OSA are needed. Fluid accumulates in the legs during the day due to gravity and whilst lying down overnight some of the fluid shifts from the legs into the neck. It is possible that increased fluid in the neck increases pressure around the throat, making it more likely to collapse and cause OSA. Compression stockings are knee-length, tight-fitting stockings which are widely used to treat various conditions, such as varicose veins and swollen legs. They work by gently compressing the legs during the day, so that fluid is unable to accumulate in the legs as it would normally. Therefore, overnight, the amount of fluid shifting from the legs towards the neck should be reduced. This may therefore reduce the amount of fluid collecting in the neck and the degree of narrowing of the throat overnight, and reduce the severity of OSA. Smaller previous studies have already shown this to be the case. The main aims of the study are to assess whether wearing compression stockings during the day for two weeks will decrease the severity of OSA and the symptoms of sleepiness associated with it.

Who can participate?
Patients aged 18 to 80 with OSA, who are not already on treatment. Patients with certain medical conditions or taking particular medications will not be allowed to take part in the study.

What does the study involve?
Participants will be randomly allocated to wear compression stockings or not, so that differences between the two groups can be compared. Participants in the compression stockings group will wear them every day for two weeks but patients in the other (control) group will not need to do anything. Participants will attend a sleep study session at the beginning and end of the two weeks. At the same time, measurements of leg and neck fluid and throat size will be taken, along with a test of alertness and questionnaires on sleepiness and activity levels.

What are the possible benefits and risks of participating?
Compression stockings are very safe and wearing them is not associated with any risks. Participants in the compression stockings group may feel better if their OSA improves.

Where is the study run from?
The Toronto Rehabilitation Institute Sleep Laboratory.

When is the study starting and how long is it expected to run for?
We will be recruiting from June 2012 for approximately 18 months and we plan to recruit 46 patients.

Who is funding the study?
The project is funded by a grant from the Canadian Institutes of Health Research.

Who is the main contact?
Dr Douglas Bradley
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Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
A randomised controlled trial of the effects of compression stockings on severity and clinical outcomes in obstructive sleep apnoea

Study objectives
In obstructive sleep apnoea (OSA) patients, daytime application of compression stockings will reduce the apnoea-hypopnoea index in association with reductions in leg fluid volume, reduction in overnight decrease in leg fluid volume, reduction in overnight increases in neck fluid volume and neck circumference and an increase in upper airway cross-sectional area. This will be further associated with improvement in sleepiness, alertness and quality of life.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University Health Network Rehabilitation Medicine and Science Research Ethics Board, 25/05/2012, ref: approval number 12-018

Study design
Single-centre randomised controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Obstructive sleep apnoea

Interventions
Compression stockings prescribed to apply pressure of 20-30 mmHg at the ankle worn during waking hours for two weeks.

The control group will not receive any treatment.

Outcomes will be measured at the end of the two weeks.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Apnoea-hypopnoea index measured at baseline and at the end of two weeks

Secondary outcome measures
Changes in:
1. Overnight change in leg and neck fluid volumes (measured by bioimpedance) and neck and calf circumferences
2. Upper airway cross-sectional area, as measured by acoustic pharyngometry
3. Sleepiness, as measured by Epworth sleepiness score
4. Quality of life, as measured by Functional Outcomes of Sleep Questionnaire-10
5. Alertness, as measured by Psychomotor Vigilance Task

Measured at baseline and at the end of two weeks

Overall study start date
01/06/2012

Completion date
01/12/2013

Eligibility

Key inclusion criteria
Men and women aged 18 to 80 years with OSA (apnoea-hypopnoea index greater than 10)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
46

Key exclusion criteria
1. Venous leg ulcers, history of peripheral vascular disease, heart failure, long-term oxygen therapy, cor pulmonale, major organ transplant, neuromuscular disease, end-stage renal disease on dialysis or adeno-tonsillar hypertrophy
2. Current use of corticosteroids or opiates
3. Treatment for OSA currently or within the last 3 months
4. Current use of compression stockings

Date of first enrolment
01/06/2012

Date of final enrolment
01/12/2013

Locations

Countries of recruitment
Canada

Study participating centre
Toronto Rehabilitation Institute
Toronto
Canada
M5G 2A2

Sponsor information

Organisation
Toronto Rehabilitation Institute

Sponsor details
550 University Avenue
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+1 (0)416 597 3422
TRI-REB@uhn.ca

Sponsor type
Hospital/treatment centre

Website
http://www.torontorehab.com

ROR
https://ror.org/00mxe0976

Funder(s)

Funder type
Government

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada)

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, IRSC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Canada

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2015		Yes	No