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Effects of weight loss on obstructive sleep apnoea syndrome (OSAS): a randomised controlled trial

Submission date	Recruitment status	[_] Prospectively registered
29/01/2009	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
13/02/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
08/12/2009	Nervous System Diseases	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Effects of a very low calorie diet (VLCD) induced weight loss on obstructive sleep apnoea syndrome (OSAS): a randomised controlled trial

Study objectives
Lifestyle modification, particularly weight loss, has been advocated as a treatment modality for obstructive sleep apnoea syndrome (OSAS). Surprisingly, there is a lack of well-conducted clinical trials; available studies have either been small and/or non-randomised. One reason could be that it has become popular to use devices such as continuous positive airway pressure (CPAP) or mandible retraction devices as mechanical tools rather than try to address the underlying problem, which generally is excess fatness in the throat area. In a report, from the International Diabetes Federation investigating the association between type 2 diabetes and sleep-disordered breathing, a number of recommendations were given. Apart from increased awareness and improved clinical practice the working party strongly suggested "appropriately powered randomised control trials of weight loss in patients with OSAS and diabetes, including the use of anti-obesity medication". The party also suggest the development of treatment programmes which are easier to use and cheaper than CPAP. In discussions with sleep apnoea experts in Sweden and the review of the literature have convinced us that there is a need for a well randomised executed study evaluating the effects of weight loss on sleep apnoea and associated sleep variables.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Regional Ethics Committee, Stockholm, approved on 28/11/2008 (ref: 2008/1634-31)

Study design
Randomised open placebo-controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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 syndrome

Interventions
Subjects will be randomly assigned to a VLCD treatment (intervention) or a control group (waiting list).

During 9 weeks the patients allocated to the intervention group will follow a VLCD-programme with 7 weeks of VLCD and 2 weeks of stabilisation. During the VLCD period the patients will receive 554 kcal per day consisting of 4 doses of commercial diet preparation (The Cambridge Diet, Cambridge Health & Weight Plan, UK). In the stabilisation phase the subjects will gradually supplement the Cambridge meals with selected foods. The patients will get an scheme from the dietician on how to reintroduce the conventional food in structured way. The allowed energy intake for each day will be specified. At the end of week 9 the patients should have reached an energy intake of 1800 kcal/day. The stabilisation phase will help to ensure long-term weight maintenance and to prevent short-term weight regain.

The control subjects will be placed on a waiting list and will be offered the same treatment as the intervention group at the end of the 9-week study period.

Both groups will after completing the VLCD period enter a weight maintenance programme in which they will receive conventional diet and exercise behaviour modification treatment at the Obesity Unit for 1 year duration. Sleep registrations will be conducted at baseline and after 9 weeks in the VLCD- and control group. The measurements will also be repeated after 1 year in the completers, i.e. the patients that completed the VLCD-period and the weight maintenance programme.

Intervention Type
Other

Phase
Not Applicable

Primary outcome measure
Improvement of OSAS defined by AHI at 9 weeks (group-time interaction). Sleep registrations will be performed in duplicate with a seven channel home polygraphy equipment (WATCH_PAT 100, Itamar Medical Ldt, and Caesarea, Israel). Channels are for snoring, body position, peripheral arterial tone (PAT), pulse, oximetry, actigraphy and sleep staging. Respiratory Disturbance Index (RDI), AHI, sleep quality and quantity are derived from the PAT-signal, oximetry and actigraphy by a well defined and validated algorithm.

Secondary outcome measures
1. To evaluate the association between concentration of ketone bodies in the blood and euphoria during weight loss and to measure, anthropometry, metabolic markers, blood pressure, physical activity, quality of life and daytime sleepiness. Mean changes between groups (intervention and control group) between baseline and endpoint will be investigated for all variables. Clinical examinations will be conducted at screening, baseline, week 1, 3, 5, 7, 9 in the VLCD- and control group. In the control group measurements will also be performed at week 18, since these measurements are the "baseline data" of the one-year maintenance programme.
2. Improvement of OSAS defined by AHI and the other factors after 1 year maintenance programme (time interaction), for methods see primary outcome

Overall study start date
10/02/2009

Completion date
10/02/2010

Eligibility

Key inclusion criteria
Amended as of 09/06/2009:
The following points of the below inclusion criteria have been amended:
1. Patients with OSAS with an Apnoea-Hypopnea Index (AHI) greater than or equal to 15
3. Aged between 30 and 65 years
All other inclusion criteria remain unaffected.

Initial information at time of registration:
1. Patients with OSAS with an Apnoea-Hypopnea Index (AHI) between 15 and 60
2. Male patients
3. Age between 30 and 60 years
4. Abdominal obesity with a Body Mass Index (BMI) 30-40 kg/m^2 and waist circumference >102 cm
5. Signed informed consent to participate in the study

Participant type(s)
Patient

Age group
Adult

Sex
Male

Target number of participants
60

Key exclusion criteria
1. Contraindications for VLCD:
1.1. Coronary thrombosis or myocardial infarct within the last three months
1.2. Cerebro-vascular accident within the last three months
1.3. Unstable ventricular arrhythmias
1.4. Major surgery or trauma within the last three months
1.5. Impaired renal or hepatic function
1.6. Severe depression
1.7. Use of mono-amine oxidase inhibitors (MAOIs)as anti-depressants
1.8. Anorexia nervosa or bulimia nervosa
1.9. Porphyria
1.10. Milk protein allergy (the diet is milk based)
1.11. Severe lactose intolerance (the diet is milk based)
1.12. (Pregnant and lactating women, children below the age of 14)
2. Drug treated diabetes
3. Currently on a weight loss drug (Acomplia®, Reductil® or Xenical®)
4. Bariatric surgery
5. Recent angina pectoris or atrial fibrillation

Date of first enrolment
10/02/2009

Date of final enrolment
10/02/2010

Locations

Countries of recruitment
Sweden

Study participating centre
Obesity Unit, m73
Stockholm
Sweden
14186

Sponsor information

Organisation
Cambridge Manufacturing Company Limited (UK)

Sponsor details
Stafford House
10 Brakey Road
Corby
Northamptonshire
United Kingdom
NN17 5LU

Sponsor type
Industry

Website
http://www.cambridge-health-plan.co.uk

ROR
https://ror.org/03haydy69

Funder(s)

Funder type
Industry

Funder Name
Cambridge Manufacturing Company Limited (UK) - main funder

Funder Name
Novo Nordisk (Denmark)

Alternative Name(s)
Novo Nordisk Global

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
Denmark

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	03/12/2009		Yes	No