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Oral mandibular advancement devices for obstructive sleep apnoea-hypopnoea

Submission date
08/03/2010

Recruitment status
No longer recruiting

Registration date
18/03/2010

Overall study status
Completed

Last Edited
26/05/2016

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Obstructive Sleep Apnoea Hypopnoea (OSAH) involves repetitive narrowing or closure of the upper airway during sleep, which results in reduced breathing (hypopnoea) or paused breathing (apnoea). This abnormal breathing causes oxygen levels to drop and leads to wakening from sleep. Sleep disturbance results in excessive daytime sleepiness, poor concentration, personality changes and irritability. In the long term there is an increased risk of heart disease and stroke in affected individuals. OSAH is a chronic condition that generally requires life-long treatment. Patients with mild OSAH are often treated conservatively with advice on weight loss, alcohol consumption and sleeping position. The standard treatment for people with moderate to severe OSAH is Continuous Positive Airway Pressure (CPAP) where air is blown into the upper airway during sleep, via either a nasal or face mask, to prevent it collapsing. However, some patients are unable to tolerate this treatment. Mild to moderate OSAH can be treated with Mandibular Advancement Devices (MAD) which hold the lower jaw and tongue forward, making more space to breathe. Research evidence indicates that CPAP is more effective than MAD and MAD is better than sham (pretend) MAD for the treatment of OSAH. Two important research questions are not answered: is MAD more effective than no treatment, and is MAD effectiveness related to device complexity? The first question is important because patients using sham MAD are likely to experience discomfort and side effects but no benefit from the sham device. This can make MAD appear more effective than it actually is. Comparing MAD to no treatment is important to ensure the benefits of MAD are not overestimated. The second question is important as there is a wide range of MADs available and it is not known which type is the most effective. The aim of this study is to evaluate the clinical effectiveness and costs in a 'real life' setting where participants may not necessarily follow the prescribed MAD treatment due to inconvenience, discomfort and other side effects.

Who can participate?
Patients aged over 18 with mild to moderate OSAH

What does the study involve?
This study compares three types of MAD:
1. Bespoke: custom made, professionally fitted
2. Semi-bespoke: commercially available postal kit where self-fit MADs are formed from a dental

impression mould used by the patient
3. Over the counter: commercially available off the shelf kit where the patient 'boils and bites' thermoplastic MAD
All participants receive four treatments (bespoke, semi-bespoke, over the counter, no treatment) for a period of 6 weeks each, in a random order. The first two weeks of this are an 'acclimatisation phase' where the patient is given the opportunity to get used to the device, followed by a 4 week 'treatment phase' where we assess how well the treatment is working. Between each treatment period there is a 1 week 'wash out' interval to ensure that any effects of the last treatment have worn off before starting a new treatment. We measure how often the patients' breathing is paused or reduced during sleep using a home portable measurement device in the final week of each treatment period. We also measure quality of life, patient symptoms and daily functioning at the end of each treatment period. Side effects experienced using each device, cost of treatment, number of withdrawals from the study and patient preference are also measured. Participants choose which device they prefer at the end of the study.

What are the possible benefits and risks of participating?
Not provided at time of registration

Where is the study run from?
Papworth Hospital (UK)

When is the study starting and how long is it expected to run for?
September 2010 to June 2012

Who is funding the study?
NIHR Health Technology Assessment Programme - HTA (UK)

Who is the main contact?
Dr Tim Quinnell

Contact information

Type(s)
Scientific

Contact name
Dr Tim Quinnell

Contact details
Respiratory Support & Sleep Centre
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Additional identifiers

Protocol serial number

HTA 08/110/03; P01415

Study information

Scientific Title
Crossover randomised controlled trial of oral mandibular advancement devices for obstructive sleep apnoea-hypopnoea

Acronym
TOMADO

Study objectives
1. Are mandibular advancement devices (MADs) more effective than no treatment?
2. Does the level of MAD sophistication - bespoke, semi-bespoke and over the counter (OTC), representing a spectrum of complexity and cost - influence treatment outcome?

More details can be found at: http://www.nets.nihr.ac.uk/projects/hta/0811003
Protocol can be found at: http://www.nets.nihr.ac.uk/__data/assets/pdf_file/0008/51992/PRO-08-110-03.pdf

Ethics approval required
Old ethics approval format

Ethics approval(s)
Cambridgeshire 2 Research Ethics Committee, 14/01/2010, ref: 10/H0308/4

Study design
Single-centre four-arm four-period crossover randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

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

Interventions
The study will compare the clinical effectiveness and costs of three types of MAD (bespoke, semi-bespoke and over the counter) and a no treatment control for participants with mild to moderate OSAH. Each 6-week period (4-week for no treatment arm) will comprise of a 2-week acclimatisation phase, followed by a 4-week treatment phase. A 1-week washout period will follow active treatments.

Intervention Type
Device

Phase
Not Specified

Primary outcome(s)
Apnoea-Hypopnoea Index (AHI). AHI is the frequency of apnoeas and hypopneas per hour of study.

Measured at baseline and then in the final week of each treatment period (5 times in total). The sleep diary will be completed daily during the treatment periods.

Key secondary outcome(s))
1. Epworth Sleepiness Scale (ESS)
2. Physiological indices from the respiratory polysomngraphy (PSG) - 4% Oxygen Desaturation Index, mean, minimum and time less than 90% of nocturnal SpO2
3. Blood pressure
4. Functional status (Functional Outcome of Sleep Questionnaire [FOSQ])
5. Generic (36-item short form health survey [SF-36]) and disease specific (Calgary Sleep Apnoea Quality of Life Index [SAQLI]) health related quality of life (HRQoL)
6. EuroQol EQ-5D transformed to the utility scale
7. Daily sleep diary (assessing adherence, hours use and retention)
8. Snoring scale (partner rated visual analogue scale)
9. Side effects, withdrawals and participant satisfaction and preference

Measured at baseline and then in the final week of each treatment period (5 times in total). The sleep diary will be completed daily during the treatment periods.

Completion date
01/06/2012

Eligibility

Key inclusion criteria
1. Aged greater than or equal to 18 years, either sex
2. Obstructive sleep apnoea-hypopnoea confirmed by respiratory polysomnogram with apnoea-hypopnoea index (AHI) 5 to 30/hours
3. Excessive daytime sleepiness (ESS) greater than or equal to 11 and/or participant reported sleepiness
4. Sufficient teeth to allow satisfactory device retention
5. Ability to give written informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex

All

Key exclusion criteria
1. Primary central sleep apnoea
2. Coexistent sleep disorder or drug treatment considered likely to have significant impact on symptoms (especially sleepiness) or MAD effectiveness
3. Severe and/or unstable cardiovascular disease judged by clinician to warrant immediate continuous positive airway pressure (CPAP)
4. Other medical or psychiatric disorder judged likely to adversely interact with MAD or confound interpretation of its effectiveness
5. Significant periodontal disease or tooth decay; partial or complete edentulism; presence of fixed orthodontic devices
6. Temporomandibular joint pain or disease
7. Severe bruxism
8. Restriction in mouth opening or advancement of mandible
9. Respiratory failure
10. Inability to give informed consent or comply with the protocol
11. Pregnant women
12. Any other significant clinical contra-indication, e.g. disabling sleepiness upgrading the obstructive sleep apnoea-hypopnoea (OSAH) to severe

Date of first enrolment
01/09/2010

Date of final enrolment
01/06/2012

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
Papworth Hospital
Cambridge
United Kingdom
CB23 3RE

Sponsor information

Organisation
Papworth Hospital NHS Foundation Trust (UK)

ROR

https://ror.org/01qbebb31

Funder(s)

Funder type
Government

Funder Name
Health Technology Assessment Programme

Alternative Name(s)
NIHR Health Technology Assessment Programme, Health Technology Assessment (HTA), HTA

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

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	01/10/2014		Yes	No
Results article	results	01/10/2014		Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes