Effects From a Mandibular Repositioning Appliance in Patients With Obstructive Sleep Apnea and Snoring

This study has been completed.

Sponsor:
Umeå University

Collaborator:
The Swedish Research Council

Information provided by (Responsible Party):
Marie Marklund, Umeå University

ClinicalTrials.gov Identifier:
NCT00477009

First received: May 21, 2007
Last updated: January 17, 2013
Last verified: January 2013

Purpose
The purpose of this study is to evaluate effects from a mandibular repositioning appliance on obstructive sleep apneas, symptoms, blood pressure and markers of stress, inflammation and cardiovascular health in patients with mild to moderate obstructive sleep apnea/hypopnea syndrome and in patients with symptomatic snoring.

<table>
<thead>
<tr>
<th>Condition</th>
<th>Intervention</th>
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</thead>
<tbody>
<tr>
<td>Sleep Apnea Syndromes Snoring</td>
<td>Device: Mandibular repositioning appliance, adjustable</td>
</tr>
<tr>
<td>Disorders of Excessive Somnolence</td>
<td></td>
</tr>
</tbody>
</table>

Study Type: Interventional

Study Design:
Allocation: Randomized
Endpoint Classification: Efficacy Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Investigator, Outcomes Assessor)
Primary Purpose: Treatment

Official Title: A Randomized Controlled Trial of Effects From a Mandibular Advancement
Device in Patients With Obstructive Sleep Apnea and Snoring

Resource links provided by NLM:

MedlinePlus related topics: Sleep Apnea Snoring

Genetic and Rare Diseases Information Center resources: Abdominal Obesity Metabolic Syndrome

U.S. FDA Resources

Further study details as provided by Umeå University:

Primary Outcome Measures:

- Sleep apnea and sleep measured by polysomnography [ Time Frame: Baseline and after 4 months ] [ Designated as safety issue: No ]
- Daytime sleepiness and sleep apnea symptoms assessed in questionnaires and objective testing [ Time Frame: Baseline and after 4 months ] [ Designated as safety issue: No ]
- Quality of life [ Time Frame: Baseline and after 4 months ] [ Designated as safety issue: No ]

Secondary Outcome Measures:

- Headaches [ Time Frame: Baseline and after 4 months ] [ Designated as safety issue: No ]
- Blood pressure [ Time Frame: Baseline and after 4 months ] [ Designated as safety issue: Yes ]
- Vigilance [ Time Frame: Baseline and after 4 months ] [ Designated as safety issue: No ]
- Markers of stress [ Time Frame: Baseline and after 4 months ] [ Designated as safety issue: No ]
- Markers of inflammation [ Time Frame: Baseline and after 4 months ] [ Designated as safety issue: No ]
- Markers of cardiovascular health and oxidative stress [ Time Frame: Baseline and after 4 months ] [ Designated as safety issue: No ]
- Side-effects from the treatment [ Time Frame: After 4 months treatment ] [ Designated as safety issue: No ]
- Predictors of effects on symptoms and sleep apneas [ Time Frame: After 4 months treatment ] [ Designated as safety issue: No ]

Enrollment: 96
Study Start Date: May 2007

Study Completion Date: December 2011

Primary Completion Date: December 2011 (Final data collection date for primary outcome measure)

<table>
<thead>
<tr>
<th>Arms</th>
<th>Assigned Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Experimental: 1</strong>&lt;br&gt;Adjustable mandibular repositioning appliance</td>
<td>Device: Mandibular repositioning appliance, adjustable&lt;br&gt;Comparison between mandibular repositioning appliance for nightly use and a placebo device regarding effects on sleep apneas and daytime symptoms as well as blood pressure and markers of oxidative stress and sleepiness.&lt;br&gt;Other Name: Herbst appliance</td>
</tr>
<tr>
<td><strong>Placebo Comparator: 2</strong>&lt;br&gt;Placebo device in upper jaw</td>
<td>Device: Mandibular repositioning appliance, adjustable&lt;br&gt;Comparison between mandibular repositioning appliance for nightly use and a placebo device regarding effects on sleep apneas and daytime symptoms as well as blood pressure and markers of oxidative stress and sleepiness.&lt;br&gt;Other Name: Herbst appliance</td>
</tr>
</tbody>
</table>

**Detailed Description:**

Mandibular repositioning appliances for the treatment of snoring and sleep apneas are increasingly used over the world, although the number of prescriptions of this therapy varies between countries. The appliance widens the upper airways during sleep in order to reduce sleep-disordered breathing. The device is easy to use and has become popular among patients. Despite this, the evidence for effects of this treatment is not very strong and based on only a few studies. The aim of this study is therefore to test the hypothesis that a mandibular repositioning appliance reduces sleep apneas, daytime sleepiness and other sleep apnea symptoms and increases the quality of life in sleepy patients with mild to moderate obstructive sleep apnea and in patients with symptomatic snoring. Secondary outcomes include effects on headaches, blood pressure and markers of stress, inflammation, cardiovascular health and oxidative stress. At baseline and after 4 month's treatment, the patients will respond to questionnaires about symptoms and quality of life. They will undergo measurements of sleepiness, sleep apneas and blood pressure as well as sampling of saliva, urine and blood. Factors that predict a successful treatment outcome will be analyzed in order to more exactly clarify the indications for this treatment modality in a group of patients who have been suggested to benefit from mandibular repositioning appliances according to previous studies and reviews.
Eligibility

Ages Eligible for Study: 20 Years to 70 Years
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:
- Obstructive sleep apnea, apnea-hypopnea index of <30 with excessive daytime sleepiness
- Snoring with excessive daytime sleepiness, apnea-hypopnea index of <5
- Body mass index of <35

Exclusion Criteria:
- Unable to give informed consent
- Psychiatric disorders including dementia that may interfere with the study protocol
- Other concomitant diseases that demand acute, effective treatment of sleep apnea
- Pharyngeal soft tissue abnormalities
- Living to far away from the University Hospital
- Professional drivers
- Pregnancy
- Included in other studies
- Other sleep apnea treatments
- Severe craniomandibular disorders
- Acute or advanced periodontal disease
- Insufficient number of teeth

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT00477009

Locations

Sweden

Depts of Respiratory Medicine and Orthodontics, Umeå University
Umeå, Sweden, SE-906 51
Sponsors and Collaborators
Umeå University
The Swedish Research Council

Investigators

Principal Investigator: Marie Marklund  Umeå University

Publications:

Responsible Party: Marie Marklund, Associate professor, Umeå University
ClinicalTrials.gov Identifier: NCT00477009  History of Changes
Other Study ID Numbers: K2007-70X-20517-01-3, Dnr 07-032M
Study First Received: May 21, 2007
Last Updated: January 17, 2013
Health Authority: Sweden: Regional Ethical Review Board
Sweden: The National Board of Health and Welfare

Keywords provided by Umeå University:
Sleep apnea syndromes  Blood pressure
Snoring  Inflammation
Mandibular advancement  Oxidative stress
Activator appliances  Hormones
Disorders of excessive somnolence  Markers of Metabolic Syndrome X

Additional relevant MeSH terms:
Apnea  Respiration Disorders
Disorders of Excessive Somnolence  Respiratory Sounds
Sleep Apnea Syndromes  Respiratory Tract Diseases
Sleep Apnea, Obstructive  Signs and Symptoms
Snoring  Signs and Symptoms, Respiratory
Dyssomnias  Sleep Disorders
Mental Disorders  Sleep Disorders, Intrinsic
Nervous System Diseases