PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Influence of an "Anti-snoring pillow" changing the head position on snoring

Trial Acronym

Anti-snoring pillow study

URL of the trial

http://Nicht vorhanden

Brief Summary in Lay Language

Primary snoring represents per se no sickness, but can often lead to social impairment. A former pilot study with the Anti-snoring pillow showed an explicit reduction in snoring. Based on the prior results, we conceived this study to evaluate the effects of the Anti-snoring pillow more precisely. The Anti-snoring pillow is built-up by in- and deflatable, small air cushions. The built-in microphones are able to detect snoring sounds and as a consequence thereof, to activate the above mentioned air cushions. The wanted effect is to reduce or even eliminate snoring by inducing a gentle change in head position. Inclusion criteria are people between 18 and 75 years, with primary snoring and ruled out sleep apnea, a BMI < = 30, an existing sleep partner and without daytime sleepiness. The study process provides a month-long test and settling-in period with the active and in-active pillow accompanied by questionnaires about sleep quality and possible complaints. At the end two nights in the sleep laboratory with active and in-active pillow follow.

Brief Summary in Scientific Language

Primary snoring represents per se no sickness. Snoring treatment strategies should therefore imply the lowest possible risk as well as being well tolerated. Besides losing weight and stick to sleep hygiene rules, there are also other therapeutic options for treating snoring like mandibular advancement devices, prevention of the supine position and surgical treatments especially of the soft palate. A reduction of snoring in case of preventing the supine position, with or without having OSA, could already be demonstrated in clinical studies. Avoiding the supine position goes along with a poor compliance due to discomfort. Anecdotal information of patients as well as clinical studies about the influence of head position on the AHI in position-dependent OSA suppose at least a snoring reduction in a lateral head position.
This study plans to evaluate the influence of changing the head position on snoring with regard to other sleep and breath-dependent parameters. The Anti-snoring pillow itself consists of two built-in microphones, incorporated in – and deflatable air-cushions with a pump, a sensor plate for the head recognition as well as a control unit. The pillow gets activated by uniform and repetitive noise

patterns up to a frequency of 500 Hz within 2 to 3 respiratory periods and initiates a change in head position. The head is kept in the position in which the recorded sound is reduced to a minimum or no longer evident. The included subjects (aged between 18 and 75, BMI<=30, primary snoring without daytime sleepiness) have to answer different questionnaires (questionnaires about the actual sleep quality, ESS questionnaire, a visual analogue scale for the assessment of snoring by patient and bed partner as well as question about sleep and snoring behaviors from the company named Sissel for participant and bed partner) prior to study start. A two-week test phase follows. Here the participants has the opportunity to test two different pillow versions, in the active and in the in-active state, a plane pillow and one with a neck support function. Thereupon a two-week settling-in period with the preferred pillow version follows, the first week with in-active pillow, the second week with active pillow, accompanied by questionnaires regarding sleep quality and tolerance after each night. Two polysomnographies according to the AASM Manual 2.0 from 2012 are planned in the sleep laboratory with active and in-active pillow in random crossover.

Organizational Data

- DRKS-ID: **DRKS00008744**
- Date of Registration in DRKS: **2015/06/17**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **2013-406M-MA , Medizinische Ethik-Kommission II Medizinische Fakultät Mannheim der Universität Heidelberg**

Secondary IDs

Health condition or Problem studied

- ICD10: **R06.5 - Mouth breathing**
- Free text: **Snoring**

Interventions/Observational Groups

- Arm 1: **In the first polysomnography night out of two, with in-active pillow, in the second with active pillow. Adaptation as well as subjective Trial period at home were ot randomised.**
- Arm 2: **In the first polysomnography night out of two, with active pillow, in the second with in-active pillow.**
  Adaptation as well as subjective Trial period at home were ot randomised.

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Other**
- Purpose: **Treatment**
- Assignment: **Crossover**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Appearance of snoring reduction: The appearance of snoring reduction will be determined by a visual analogue scale, that test person and bed partner are going to fill out prior to study start, as well as after completion of the on month lasting test and settling-in period. Furthermore the snoring – index is taking into consideration, which will be ascertained during the two polysomnography nights in the sleep laboratory.

Secondary Outcome

Alteration of sleep quality: During the settling-in period, questions on “falling asleep easily”, “lying down and sleeping as usual”, “being tired the next morning, exhausted, irritable“, “being disturbed by the pillow while sleeping“ and “sleeping through“ has to be answered after each night for evaluating the sleep quality. Further on questionnaires regarding daytime sleepiness via ESS (Epworth Sleepiness Scale) and sleep quality will be handed over prior to study start and afterwards.
Evaluation of the polysomnographic sleep- and breath-related parameters, like AHI (apnea-hypopnea-Index), AHI in supine position, RERAS (Respiratory Effort-Related Arousals).

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **HNO - Klinik, Schlafmedizinisches Zentrum, Mannheim**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2013/07/12**
- Target Sample Size: **20**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **75 Years**

Additional Inclusion Criteria

**Patients / participants with primary snoring (Obstructive sleep apnea was ruled out previous to the study by polysomnography or respiratory polygraphy)
aged between 18 and 75
body mass index (BMI) <= 30
without daytime sleepiness and
an existing bed partner**

Exclusion criteria

**Aged <17 and >75
BMI>30
obstructive sleep apnea or persistent daytime sleepiness (ESS>12)**

Addresses

- **Primary Sponsor**

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  Fax: **[---]***
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  URL: **[---]***
- **Contact for Scientific Queries**

Contact for Scientific Queries

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Sources of Monetary or Material Support

- **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

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Fax: **[---]***
E-mail: **[---]***
URL: **[---]***

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2014/02/05**

Trial Publications, Results and other documents

- Approval of ethics comm. (mandatory for transfer to Studybox) **Published 2017 in "Sleep and Breathing"**

** This entry means the parameter is not applicable or has not been set.*

**** This entry means that data is not displayed due to insufficient data privacy clearing.*