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

Trial Description

Title

Prevalence of the obstructive sleep apnoea syndrom in patients at general practitioners with first diagnosis of arterial hypertension

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

The high blood pressure disease is associated with many different diseases that can also be a cause of the disease. It was found that the sleep-related breathing disorder belong. However, a study on this by the German guidelines only in patients is recommended where there are problems such as snoring, daytime sleepiness, or breathing pauses. The most important sleep-related breathing disorder is obstructive sleep apnea syndrome (OSAS). It comes in your sleep to obstruction of the airways, which leads to a wake-up reaction and release of stress hormones. This may be the cause of high blood pressure disease.

In this study we want to check whether it is useful to examine high blood pressure patients who do not have corresponding symptoms. To this end, the sleep of these patients will be monitored at home using a special device. This is called sleep apnea screening. Using this screening can identify patients with a sleep related breathing disorder and so treat the possible cause of high blood pressure.

Brief Summary in Scientific Language

**In the western industrialized countries 20-30% of the population suffer from sleep disturbances or sleep-related disorders. The most common
are the sleep-disordered breathing, particularly obstructive sleep apnea syndrome (OSAS), in which
repeatedly interrupted the respiratory flow due to partial or complete transfer of the pharyngeal airway
will. Obstructive sleep apnea (OSA) occurs in hypertensives on much more frequently than in the general population. Epidemiological studies from the U.S. show that about 50% of patients
suffer with hypertension in OSA. Nevertheless, the general investigation on the OSA at initial diagnosis "hypertension in the German guidelines is not provided.**

Only with a clinical suspicion of secondary hypertension and a history of appropriate screening is provided.

The study is to be checked whether the current German guidelines for evaluation

of OSAS are sufficient. Maybe it comes with a lack of general screening to a delayed diagnosis. It is expected that even with an unremarkable medical history, the prevalence of OSA is significantly higher in patients with newly diagnosed hypertension than in the general population.

Organizational Data

- DRKS-ID: **DRKS00005634**
- Date of Registration in DRKS: **2014/07/10**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **182/12 , Ethik-Kommission der Medizinischen Fakultät der Rheinischen Friedrich-Wilhelms-Universität Bonn**

Secondary IDs

Health condition or Problem studied

- ICD10: **I10 - Essential (primary) hypertension**
- ICD10: **G47.31 - [generalization G47.3: Sleep apnoea]**

Interventions/Observational Groups

- Arm 1: **24-hour long-term blood pressure measurement - with a mean blood pressure of at least RR 135/80 mmHg is an outpatient sleep apnea screening with the "SOMNOcheck effort" Weinmann conducted.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Screening**
- Assignment: **Single (group)**
- Phase: **N/A**

Study Type: **Non-interventional**

Study Type Non-Interventional: **Other**

Allocation: **Single arm study**

Blinding: **[---]***

Who is blinded: **[---]***

Control: **Uncontrolled/Single arm**

Purpose: **Screening**

Assignment: **Single (group)**

Phase: **N/A**

- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Presence of sleep apnea syndrome in ambulatory measurement with the SOMNOcheck effort "Weinmann.

Secondary Outcome

On the day of the sleep apnea screening, the patient received two questionnaires: the Epworth Loveliness Scale (ESS) for the detection of daytime sleepiness and the Pittsburgh Sleep Quality Index (PSQI), which detects the quality of sleep in the last four weeks.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Doctor's Practice **Linz**
- Doctor's Practice **Bad Honnef**
- Doctor's Practice **Bonn-Ippendorf**
- Doctor's Practice **Bonn-Zentrum**
- Doctor's Practice **Bonn-Dransdorf**
- Doctor's Practice **Bonn-Tannenbusch**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2012/12/03**
- Target Sample Size: **50**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **85 Years**

Additional Inclusion Criteria

Patients with elevated RR values (> 140/90) on two different days in the GP practice and the lack of blood pressure therapy

Exclusion criteria

malignant disease, pregnancy, antihypertensive treatment

Addresses

- **Primary Sponsor**

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Sources of Monetary or Material Support

- **Institutional budget, no external funding (budget of sponsor/PI)**

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Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2014/05/07**

Trial Publications, Results and other documents