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

Trial Description

Title

Extended validation of the auto-Bi/TriLevel therapy modes prismaLINE

Trial Acronym

prismaLINE auto-Bi/TriLevel Studie

URL of the trial

[---]*

Brief Summary in Lay Language

In the treatment of sleep related breathing disorders (SRBDs) distinct forms of therapy with positive airway pressure (PAP) are applied. During BiLevel therapy pressure levels differ between expiration and inspiration and are applied by means of a respiratory mask. Application of different pressure levels during expiration and inspiration enables administration of ventilatory support as well as treatment of respiratory disturbances during sleep. In recent years BiLevel devices with auto-regulation have become established on the market. These devices detect the respiratory flow as well as breathing disturbances and adjust the applied therapeutic pressure and device behavior according to treatment needs. This study aims at investigating the efficacy of the auto-adaptive regulation of an auto-BiLevel device during treatment initiation in sleeb laboratory settings. In addition an extension of the classic BiLevel pressure profile is evaluated.

Brief Summary in Scientific Language

Auto-BiLevel therapy is an established treatment form for sleep related breathing disorders (SRBDs). Among other indications, BiLevel therapy is applied for treatment of patients with obstructive sleep apnea (OSA) and high pressure needs. It is further used for treatment of patients with mixed or complex sleep apnea as well as hypoventilation, e.g. obesitas hypoventilation syndrome (OHS) or overlap patients. BiLevel devices of the prismaLINE platform (Weinmann) provide the option to apply an auto-adaptive regulation. An additional option is the possibility to apply an extension of the classic BiLevel pressure profile, the TriLevel pressure profile. During TriLevel treatment application of the critical therapeutic pressure for obstruction treatment is constrained to the end-expiratory phase, which is susceptible to the generation of obstructions. Therapy pressure at beginning of expiration is decreased up to 4hPa. This aims at increasing therapy comfort and at reducing average and peak therapeutic pressure. In this national multicenter clinical trial the therapeutic efficacy of the applied pressure profiles of the auto-BiLevel therapy modes (prismaLINE platform, Weinmann) is further validated. In addition, this study aims at obtaining further information regarding the quality of event-recognition, the pressure ramp to

inspiration and trigger behavior at different respiratory profiles and artifact situations. A secondary aim is the exploratory comparison of the Bi- and TriLevel pressure-profile regarding the efficacy of obstruction treatment and ventilatory efficacy. To do so, a randomized split-night application of each pressure profile is addministered. In total, the acquisition of minimal 80 up to maximal 150 patients is planned.

Organizational Data

- DRKS-ID: **DRKS00007994**
- Date of Registration in DRKS: **2015/06/11**
- 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.: **112/2014 , Ethik-Kommission der Universität Witten/Herdecke**

Secondary IDs

Health condition or Problem studied

- Free text: **Sleep Related Breathing Disorders (SRBDs), Patients with the indication for first-time initiation of BiLevel therapy.**
- ICD10: **G47.3 - Sleep apnoea**

Interventions/Observational Groups

- Arm 1: **Application of the TriLevel pressure profile during one half (split-night) of a treatment night with polysomnography in a sleep laboratory.**
- Arm 2: **Application of the BiLevel pressure profile during one half (split-night) of a treatment night with polysomnography in a sleep laboratory.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Other**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control (effective treament of control group)**

Study Type: **Interventional**

Study Type Non-Interventional: **[---]***

Allocation: **Other**

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

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

Control: **Active control (effective treament of control group)**

- Purpose: **Treatment**
- Assignment: **Crossover**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Primary outcome parameters for the evaluation of therapeutic efficacy of the auto-Bi-/TriLevel therapy night are the apnea-hypopnea index (AHI) and the percentage of total sleep time (TST) with an oxygen Saturation < 90% (SpO2<90% in %TST).

Secondary Outcome

Outcome parameters of the split-night comparison of the Bi- and TriLevel pressure profile are the obstructive apnea index (oAI) and the percentage of total sleep time (TST) with an oxygen saturation < 90% (SpO2<90% in %TST). In addition the following outcome parameters are of relevance for the comparison: tidal volume, breaths per minute (bpm), pressure parameters (IPAP, EEPAP, EPAP), leakage and relative inspiration time (Ti/T). The outcome parameters and laboratory reports regarding evtl. manual changes of therapeutic parameters will provide information regarding the comparison of the Bi- and TriLevel pressure profile.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **HELIOS Klinik Hagen-Ambrock, Hagen**
- Medical Center **Evangelisches Krankenhaus Herne, Herne**
- Medical Center **Städtisches Klinikum Karlsruhe , Karlsruhe**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/04/01**
- Target Sample Size: **80**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Diagnosis of obstructive, mixed or complex sleep apnea; indication for first-time initiation of BiLevel therapy within clinical routine, time to first time diagnosis ≤ 6 months; Age ≥ 18 years; signed informed consent

Exclusion criteria

Missing signed informed consent form; Concurrent participation in another study that influences the initiation of BiLevel therapy by specifications of device settings or titration procedure; Acute cardiac decompensation; Severe arrhythmia; Severe hypotension, particularly in combination with intravascular volume depletion; Severe epistaxis; High risk of barotrauma; Severe chronic/decompensated pulmonary conditions; Pneumothorax or pneumomediastinum; Pneumocephalus; Cranial trauma; Status following brain surgery or surgical intervention on the pituitary gland or the middle/inner ear; Acute sinus infection (sinusitis), middle ear infection (otitis media) or perforated eardrum; Dehydration; In each case the decision whether to use this therapy device lies with the doctor in charge.

Addresses

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Sources of Monetary or Material Support

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

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URL: **[---]***

Status

- Recruitment Status: **Recruiting stopped after recruiting started**
- Study Closing (LPLV): **2016/01/15**

Trial Publications, Results and other documents

** 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.*