PLEASE NOTE: *This study has been imported from ClinicalTrials.gov without additional data checks.*

Trial Description

Title

Phase III Study on Alternative Dosing Regimens in the Pharmacotherapy of Mild to Moderate Insomnia

Trial Acronym

ALPHASOM

URL of the trial

[---]*

Brief Summary in Lay Language

The purpose of this study is to evaluate whether drug efficiency of zolpidem and amitriptyline can be conditioned according to learning theory in patients with primary insomnia.

Brief Summary in Scientific Language

Previous research has shown that repeated drug treatments can be regarded as conditioning processes. Sleep disorders are especially of interest to be investigated under the perspective of conditioning with drugs, since sleep quality can be defined both in terms of subjective ratings (self-rated sleep quality parameters) and objective measures (via polysomnographic assessment PSG; e.g., total sleep time, sleep onset, sleep architecture).
By using two different drugs (zolpidem, amitriptyline) that modulate sleep differentially, the investigators intend to implement a conditioning paradigm in sleep disorders dissociating conditioning effects on subjective and objective sleep parameters. Both drugs should affect objective and subjective sleep parameters positively, while only amitriptyline should modulate the objectively assessed sleep architecture by REM-suppression (latency of REM-sleep onset, percentage of REM-sleep).Patients with mild to moderate insomnia will undergo a classical conditioning paradigm with one of two study medications:

**amitriptyline
or zolpidem. After an acquisition period and a wash-out period, conditioned sleep changes
are assessed in an evocation trial. During a second treatment phase of 7 days, patients
receive different doses of amitriptyline (between 0mg and 50mg per night) or zolpidem
(between 0mg and 5mg per night) to evaluate alternative dosing regimens in the
pharmacotherapy of mild to moderate Insomnia.**

Organizational Data

- DRKS-ID: **DRKS00007239**
- Date of Registration in DRKS: **2015/05/06**
- Date of Registration in Partner Registry or other Primary Registry: **2014/04/24**
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- EudraCT-No.
(for studies acc. to Drug Law): **2013-003229-27**
- Primary Registry-ID: **NCT02139098 (ClinicalTrials.gov)**
- Sponsor-ID: **FOR1328-SP8 (Philipps University Marburg Medical Center)**
- Other Secondary-ID: **2013-003229-27**

Health condition or Problem studied

- Free text: **Insomnia**
- ICD10: **F51.0 - Nonorganic insomnia**

Interventions/Observational Groups

- Arm 1: **Drug: Amitriptyline**
- Arm 2: **Drug: Zolpidem**
- Arm 3: **Drug: Amitriptyline**
- Arm 4: **Drug: Placebo**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **patient/subject, caregiver, investigator/therapist, assessor**
- Control: **Placebo, Active control**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **III**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

- Objective Total Sleep Time; time frame: Change from baseline to day 10 after first medication intake; assessed by polysomnography
- Objective Sleep Onset Latency; time frame: Change from baseline to day 10 after first medication intake; assessed by polysomnography
- Self-reported Total Sleep Time; time frame: Change from baseline to day 10 after first medication intake; assessed by sleep diary
- Self-Reported Sleep Onset Latency; time frame: Change from baseline to day 10 after first medication intake; assessed by sleep diary

Secondary Outcome

- Percentage of REM sleep; time frame: Change from baseline to day 10 after first medication intake; assessed by polysomnography
- REM onset latency; time frame: Change from baseline to day 10 after first medication intake; assessed by polysomnography
- Objective Sleep Efficiency; time frame: Change from baseline to day 17 after first medication intake; assessed by actigraphy
- Objective Total Sleep Time; time frame: Change from baseline to day 17 after first medication intake; assessed by actigraphy
- Self-Reported Total Sleep Time; time frame: Change from baseline to day 18 after first medication intake; assessed by sleep diary
- Self-reported Sleep Onset Latency (min); time frame: Change from baseline to day 18 after first medication intake; assessed by sleep diary
- Self-reported Sleep Onset Latency (evaluation); time frame: Change from baseline to day 18 after first medication intake; assessed by sleep diary

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- **Clinical Psychology and Psychotherapy, Department of Psychology, Philipps University Marburg, Marburg**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2014/05/31**
- Target Sample Size: **150**
- Monocenter/Multicenter trial: **[---]***
- National/International: **[---]***

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **69 Years**

Additional Inclusion Criteria

1. age between 18 years to 69 years

2. fluent in German language

3. provide written informed consent

4. ability to understand the explanations and instructions given by the study physician and the investigator

Exclusion criteria

1. Sleep disorders caused by medical factors (e.g. sleep apnea, restless legs syndrome, narcolepsy, substance-induced insomnia)

2. Contraindications to study medication intake according to the information sheet for health professionals (Summary of medicinal Product Characteristics, SmPC; Fachinformation in Germany) assessed by physical examination (including ECG) and medical history

- allergies to amitriptyline hydrochloride or any of its ingredients

- allergies to zolpidem or any of its ingredients

- acute intoxication with alcohol, analgetics, hypnotics or any other psychotropic drug

- urinary retention

- delirium

- untreated closed-angle glaucoma

- prostatic hyperplasia

- pyloric stenosis

- paralytic ilius

- suicidal thoughts

- liver/ kidney/ pulmonary insufficiency

- myasthenia gravis

- hypokalemia

- bradycardia

- coronary heart disease, cardiac arrhythmias, long QT syndrome or other clinically relevant cardiac disorders

- increased risk of seizures/ history of seizures

- substance dependence syndrome/ history of substance dependence syndrome

3. Allergies to ingredients of placebo or novel-tasting drink (CS)

4. currently pregnant (verified by urine pregnancy test) or lactating

5. patients scoring ≥12 on the Epworth Sleepiness Scale

6. patients scoring below 8 or above 21 on the Insomnia Severity Index

7. patients suffering from a mental disorder as verified by the SCID (major depression; psychosis; brain injury; substance abuse or dependency syndrome during the last 6 months before V1)

8. nicotine consumption > 10 cigarettes/day

9. unwillingness to refrain from alcohol consumption throughout the study

10. Concomitant medication interfering with study medication intake due to potential interactions (all psychotropic medication including analgetics and muscle relaxants, hypericum derivatives; antihypertensives; anti-arrhythmic agents; antibiotics; cisaprid; anti-malaria drugs; diuretics; imidazole antifungals; cumarin derivatives; antihistaminics; calcium channel blockers; medications that enlarge the QT interval or may lead to hypokalemia)

11. change in concomitant medication regime during the last 2 weeks prior to visit 1 or after randomization

12. intake of psychotropic medication during the last 3 months

13. participation in any other clinical trial 3 months prior to visit 1

14. women of childbearing age not using 2 highly effective contraceptive methods

15. employee of the Sponsor or the principal investigator

Addresses

- **Primary Sponsor**

  Philipps University Marburg Medical Center

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

- **Contact for Scientific Queries**

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- **Collaborator, Other Address**

Philipps University Marburg Coordination Centre for Clinical Trials

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

Sources of Monetary or Material Support

- **[---]***

Bitte wenden Sie sich an den Sponsor / Please refer to primary sponsor

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

Status

- Recruitment Status: **Recruiting ongoing**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

The parameters in ClinicalTrials.gov and DRKS are not identical. Therefore the data import from ClinicalTrials.gov required adjustments. For full details please see the DRKS FAQs.
- Translation on version: 1
- Last processed date by ClinicalTrials.gov: 2014/11/05

** 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.*