Trial Description

Title

Circadian Data Collection from Sleep-Onset Insomnia Patients

Trial Acronym

CDC_SOIP

URL of the trial

[---]*

Brief Summary in Lay Language

The purpose of this trial is to test the use of a statistical model involving actigraphy, light exposure, and heart rate variability to estimate circadian phase in patients with sleep-onset insomnia.

Background: Human beings possess an internal biological clock which influences many physiological and behavioral processes such as temperature, hormone levels, sleep/wake cycle, and heart rate. If there is a significant misalignment between the biological clock and the solar clock, this can lead to several disorders such as insomnia and depression. In order to determine the presence of a mislignment, the circadian phase of the person must be determined. This is currently done in a sleep lab using saliva or blood samples to assess the levels of melatonin. This procedure is time consuming, impractical, and expensive. We are attempting to replace this procedure with the use of a mathematical model which uses data collected non-invasively in ambulatory conditions.

Protocol: Patients diagnosed with sleep-onset insomnia will be asked to wear an Actiwatch for a total of 7 days. On the 6th day, the patients will come to the lab and will be connected to an ambulatory heart rate monitor. On that same evening, hourly saliva samples will be collected in order to determine the levels of melatonin. The patients will spend the night in the clinic, where a polysomnogram will be recorded. On the 7th day, the patients will be allowed to carry out their normal routine while still wearing the Actiwatch and heart rate monitor. They will return in the evening after at least 26 hours of heart rate has been recorded. At this time, all devices will be returned and the data collection will be completed.

Population: Twenty male and female patients diagnosed with sleep-onset insomnia between 18 and 65 years of age will be recruited. They must not have any diagnosed neurological, psychiatric, or cardiovascular disorders. They must not suffer from sleep apnea or restless legs syndrome. They must not be taking any sleep medication or antidepressants. They must not have taken part in shift work or traveled across more than 2 timezones in the last 2 weeks. And they must not be caretakers of babies or very small children.

Outcome: This study will be a data collection which results in actigraphy, heart rate, melatonin, and sleep data from sleep-onset insomnia patients. This data will then be used to test and train mathematical models used to estimate circadian phase in ambulatory conditions.

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Brief Summary in Scientific Language

The purpose of this trial is to test the use of a statistical model involving actigraphy, light exposure, and heart rate variability to estimate circadian phase in patients with sleep-onset insomnia.

Background: Human beings possess an internal biological clock located in the suprachiasmatic nuclei which influences many physiological and behavioral processes such as temperature, hormone levels, sleep/wake cycle, and heart rate. If there is a significant misalignment between the biological clock and the solar clock, this can lead to several disorders such as insomnia and depression. In order to determine the presence of a mislignment, the circadian phase of the person must be determined. This is currently done in a sleep lab using saliva or blood samples to assess the levels of melatonin. From this melatonin profile, the dim light melatonin onset (DLMO) can be calculated. DLMO is the gold standard in circadian phase. This procedure is time consuming, impractical, and expensive.

We are attempting to replace this procedure with the use of a statisticall trained mathematical model which uses data collected non-invasively in ambulatory conditions.

Protocol: Patients diagnosed with sleep-onset insomnia will be asked to wear an Actiwatch for a total of 8 days. On the 7th day, the patients will come to the lab and will be connected to an Holter ECG monitor. On that same evening, hourly saliva samples will be collected in order to determine the levels of melatonin. The patients will spend the night in the clinic, where a PSG will be recorded. On the 8th day, the patients will be allowed to carry out their normal routine while still wearing the Actiwatch and ECG monitor. They will return in the evening after at least 26 hours of heart rate has been recorded. At this time, all devices will be returned and the data collection will be completed.

Population: Twenty male and female patients diagnosed with sleep-onset insomnia between 18 and 65 years of age will be recruited. They must not have any diagnosed neurological, psychiatric, or cardiovascular disorders. They must not suffer from sleep apnea or restless legs syndrome. They must not be taking any sleep medication or antidepressants. They must not have taken part in shift work or traveled across more than 2 timezones in the last 2 weeks. And they must not be caretakers of babies or very small children.

Outcome: This study will be a data collection which results in actigraphy, ECG, melatonin, and PSG data from sleep-onset insomnia patients. This data will then be used to test and train mathematical models used to estimate circadian phase in ambulatory conditions.

Organizational Data

- DRKS-ID: **DRKS00005629**
- Date of Registration in DRKS: **2014/01/21**
- 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.: **EA1/206/13 , Ethik-Kommission der Charité - Universitätsmedizin Berlin-**

Secondary IDs

Health condition or Problem studied

- ICD10: **G47.0 - Disorders of initiating and maintaining sleep [insomnias]**
- ICD10: **G47.2 - Disorders of the sleep-wake schedule**

Interventions/Observational Groups

- Arm 1: **circadian data from sleep-onset insomnia patients**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Basic research/physiological study**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

The ECG and actigraphy data will be used to train and test mathematical models to estimate circadian phase. The output of the models will be compared to the reference value, DLMO.

Secondary Outcome

Insights into the differences in HRV features in healthy versus sleep-onset insomnia patients will be assessed.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Charite and Advanced Sleep Research (ASR), Berlin**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2014/01/20**
- Target Sample Size: **20**
- Monocenter/Multicenter trial: **Monocenter trial**

Planned/Actual: **Planned**

(Anticipated or Actual) Date of First Enrollment: **2014/01/20**

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: **65 Years**

Additional Inclusion Criteria

Diagnosed sleep-onset insomnia

Exclusion criteria

Diagnosed neurological, psychiatric, cardiovascular disorders. Diagnosed sleep apnea or restless legs syndrome. Use of sleep or antidepressants. Shift workers. Caretaker of babies or small children. Having travelled across 2 or more time yones in the past 2 weeks. Drug or excessive alcohol consumption. Caffeine consumption above 350mg per day. Frequent exercisers (>4hours/week).

Addresses

- **Primary Sponsor**

Philips Research Eindhoven
High Tech Campus 34
5656AE Eindhoven
Netherlands

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

- **Contact for Scientific Queries**

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5656AE Eindhoven
Netherlands

Telephone: **+31631784276**
Fax: **[---]***
E-mail: **enrique.gil at philips.com**
URL: **[---]***

Sources of Monetary or Material Support

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

Philips Research Eindhoven
High Tech Campus 34
5656AE Eindhoven
Netherlands

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

■ **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

Marie Curie Actions
Brussels
Belgium

Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)

Marie Curie Actions
Brussels
Belgium

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

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2014/06/25**

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.*