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

Trial Description

Title

Activity of stress-related systems, metabolic consequences and genetics of restless legs syndrome, periodic limb movements, parasomnias, narcolepsy and healthy controls

Trial Acronym

ASS

URL of the trial

[---]*

Brief Summary in Lay Language

We use simple, but standardized methods to monitor the activity of stress-related hormones in patients of the sleep laboratory of the central institute of mental health. Also, we collect blood for the investigation of metabolic disturbances and genetic analyses. Thereby, a large number of samples of patients with various sleep disorders is availabe to study the relationship between sleep disorders and consecutive medical disorders.

Brief Summary in Scientific Language

We generate a biobank with samples of patients with various sleep disorders and healthy controls. We intend to study the relationship between stress hormones (e.g. cortisol in urine) and metabolic as well as endocrine disorders. Also, we collect DNA for future genetic analyses.

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00008902**
- Date of Registration in DRKS: **2015/07/13**

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Date of Registration in DRKS: **2015/07/13**

- 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.: **2011-315N-MA , Medizinische Ethik-Kommission II Medizinische Fakultät Mannheim der Universität Heidelberg**

Secondary IDs

Health condition or Problem studied

- ICD10: **F51.0 - Nonorganic insomnia**
- ICD10: **G25.8 - Other specified extrapyramidal and movement disorders**
- ICD10: **G47.4 - Narcolepsy and cataplexy**

Interventions/Observational Groups

- Arm 1: **primary insomnia (analysis of existing blood samples)**
- Arm 2: **Restless legs syndrome (analysis of existing blood samples)**
- Arm 3: **narcolepsy + other parasomnias (analysis of existing blood samples)**
- Arm 4: **healthy controls (analysis of existing blood samples)**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Other**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Other**
- Purpose: **Basic research/physiological study**
- Assignment: **Other**
- Phase: **N/A**

Study Type: **Non-interventional**

Study Type Non-Interventional: **Observational study**

Allocation: **Other**

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

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

Control: **Other**

Purpose: **Basic research/physiological study**

Assignment: **Other**

Phase: **N/A**

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

Primary Outcome

Endpoints are metabolic features (cholesterol, fasting glucose etc.) and endocrinological parameters (adipokines, BDNF and others) in blood samples that are collected in the framework of a clinical routine blood withdrawal. Relevant endpoints are laboratory features of the metabolic syndrome (triglycerides, LDL-, HDL- and total cholesterol, fasting glucose) as well as endocrinological variables like adipokines (proteins secreted by fat tissue like leptin, adiponektin) and growth factors, like insulin-like growth factor-1 (IGF-1) and brain-derived neurotrophic factor (BDNF). Cortisol in night urine is an independent variable, which - as well as polysomnography and clinical diagnoses - is relevant for the determination of study groups.

Secondary Outcome

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Zentralinstitut für Seelische Gesundheit, Mannheim**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2011/08/25**
- Target Sample Size: **1000**

Planned/Actual: **Actual**

(Anticipated or Actual) Date of First Enrollment: **2011/08/25**

Target Sample Size: **1000**

- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

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

Additional Inclusion Criteria

patients with sleep disorder (see above) that is confirmed by polysomnography

Exclusion criteria

inability to consent

Addresses

- **Primary Sponsor**

Zentralinstitut für Seelische Gesundheit
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- **Contact for Scientific Queries**

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Sources of Monetary or Material Support

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

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

Status

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

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.*