

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

Trial Description

Title

Evaluation study of prevalence of sleep-disordered breathing in patients requiring surgical myocardial revascularization and analysis of incidence of postoperative atrial fibrillation in associated with sleep-disordered breathing

Trial Acronym

SDB-CABG-BO1

URL of the trial

[---]*

Brief Summary in Lay Language

Sleep-disordered breathing is highly common in patients with cardiovascular disease and sleep-disordered breathing is believed to promote cardiac dysrhythmia. Postoperative cardiac dysrhythmia after heart surgery is a major comorbidity resulting in prolonged ICU (Intensive Care Unit) or Hospital stay and even has impact on survival. Scientific literature on prevalence of sleep-disordered breathing in patients with cardiovascular disease requiring heart surgery is scarce and its association with incidence of postoperative atrial fibrillation is not well studied. This study aims to prospectively investigate prevalence of sleep-disordered breathing in patients with cardiovascular disease

Brief Summary in Scientific Language

Sleep-disordered breathing is highly common in patients with cardiovascular disease and sleep-disordered breathing is believed to promote cardiac dysrhythmia. Postoperative cardiac dysrhythmia after heart surgery is a major comorbidity resulting in prolonged ICU or Hospital stay and even has impact on survival. Scientific literature on prevalence of sleep-disordered breathing in patients with cardiovascular disease requiring heart surgery is scarce and its association with incidence of postoperative atrial fibrillation is not well studied. This study aims to prospectively investigate prevalence of sleep-disordered breathing in patients with cardiovascular disease requiring heart surgery and

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00014665**
- Date of Registration in DRKS: **2018/05/14**
- 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.: **17-262 , Ethikkommission der Medizinischen Fakultät der Ruhr-Universität Bochum, Sitz Bad Oeynhausen**

Secondary IDs

Health condition or Problem studied

- ICD10: **G47.3 - Sleep apnoea**
- ICD10: **I48 - Atrial fibrillation and flutter**

Interventions/Observational Groups

- Arm 1: **This study prospectively investigates prevalence of sleep-disordered breathing in patients undergoing heart surgery for myocardial revascularization of coronary artery disease. All patients older than 18 years and willing to participate in this study will receive an unattended cardiorespiratory polygraph prior to heart surgery. This study will then analyze associations of sleep-disordered breathing with incidence of postoperative**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Single arm study**
- Blinding: [---]*
- Who is blinded: [---]*
- Control: **Uncontrolled/Single arm**
- Purpose: **Diagnostic**
- 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: **Diagnostic**

Assignment: **Single (group)**

Phase: **N/A**

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

Primary Outcome

Prevalence of sleep-disordered breathing in patients undergoing heart surgery and collection of electrocardiographical rate of postoperative onset of atrial

Secondary Outcome

Investigation whether onset of postoperative atrial fibrillation has influence of the length of ICU (Intensive Care Unit) or hospital stay and whether additional examinations or procedures become necessary such as cardioversion, additional

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Herz- und Diabeteszentrum Nordrhein-Westfalen, Bad Oeynhausen**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2018/01/01**
- 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

No known atrial fibrillation, planned heart surgery, no known sleep-disordered breathing with and without treatment

Exclusion criteria

Known atrial fibrillation, known sleep-disordered breathing with and without

Addresses

■ Primary Sponsor

**Herz- und Diabeteszentrum Nordrhein-Westfalen
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■ Contact for Scientific Queries

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■ Contact for Public Queries

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Sources of Monetary or Material Support

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

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E-mail: [---]*

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Status

- Recruitment Status: **Recruiting ongoing**
- Reason, if "Recruitment stopped after recruiting started" or "Recruiting withdrawn before recruiting started": [---]*
- Reason, if Reason for Recruiting Stop "Other": [---]*
- Study Closing (LPLV): [---]*
- Number of Participants in Germany after Recruiting complete: [---]*
- Total Number of Participants (all Sites worldwide) after Recruiting complete: [---]*

Trial Publications, Results and other documents

DRKS-ID: **DRKS00014665**

Date of Registration in DRKS: **2018/05/14**

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Deutsches Register
Klinischer Studien

German Clinical
Trials Register

* *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.*