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

Trial Description

Title

Supervised Obesity Reduction Trial for AF Ablation Patients

Trial Acronym

SORT-AF

URL of the trial

[---]*

Brief Summary in Lay Language

Study hypothesis:

Weight reduction in obese patients with atrial fibrillation. Obese patients benefit from an obesity treatment after atrial fibrillation ablation.

Study design:

A prospective randomized, open-lable clinical trial.

Study protocol:

The purpose of this study is to proof a professional care of overweight patients with symptomatic atrial fibrillation, as well as the treatment of the risk factors for atrial fibrillation, especially obstructive sleep apnea and hypertension.

There is a 1:1 randomization. In the intervention group, patients are followed up in a 6-month intensive care after atrial fibrillation ablation. During the follow up time patients will visit the nutritional advice every two weeks for 6 months.

The Follow-up in the control group is standard of care. At baseline, a screening test for obstructive sleep apnea and arterial hypertension will be performed as standard care.

The documentation of atrial fibrillation after ablation is made possible by the implantation of an event recorder before atrial fibrillation ablation.

Follow up:

A follow-up will be performed after 3,6 and 12 months in both groups. Patients in the intervention group will be followed-up every 2 weeks in the first 6 months.

Brief Summary in Scientific Language

[---]*

Organizational Data

- DRKS-ID: **DRKS00005868**
- Date of Registration in DRKS: **2014/09/10**
- Date of Registration in Partner Registry or other Primary Registry: **2014/02/13**
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- Primary Registry-ID: **NCT02064114 (ClinicalTrials.gov)**
- Sponsor-ID: **PV4300 (Universitätsklinikum Hamburg-Eppendorf)**

Health condition or Problem studied

- Free text: **Atrial Fibrillation**
- Free text: **Obesity**
- Free text: **Sleep Apnea**
- ICD10: **I48 - Atrial fibrillation and flutter**
- ICD10: **E66 - Obesity**
- ICD10: **G47.3 - Sleep apnoea**

Interventions/Observational Groups

- Arm 1: **Procedure: Intervention group**
- Arm 2: **Procedure: control group**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

- Recurrence of sustained atrial fibrillation; time frame: 12 months; Recurrence of sustained atrial fibrillation (>30 seconds) after atrial fibrillation ablation

Secondary Outcome

- Coincidence of sleep apnea; time frame: 12 months

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- **Universitätsklinikum Hamburg-Eppendorf, Hamburg**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2014/01/31**
- Target Sample Size: **140**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **80 Years**

Additional Inclusion Criteria

- Age ≥ 18 years

- Overweight with a BMI ≥ 30

- Obtained written informed consent

- Symptomatic atrial fibrillation with indication for ablation

Exclusion criteria

- Age <18 years

- Permanent atrial fibrillation (failed Cardioversion or episode duration > 12 months)

- Previous surgical or interventional therapy of atrial fibrillation

- BMI > 40

- Pregnant women or women of childbearing potential without a negative pregnancy test within 48 hours prior to treatment

- History of hemorrhagic diathesis or other coagulopathies

- Contraindications for oral anticoagulation

- Hyper- or hypothyroidism

- Drug or chronic alcohol abuse

- Has any condition that would make participation not be in the best interest of the subject

- Incompliants

- Unable to perform athletic exercise due to disease or disability

- Resident outside Hamburg

Addresses

- **Primary Sponsor**

  Universitätsklinikum Hamburg-Eppendorf

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **[---]***
- **Contact for Scientific Queries**

  University Heart Center Hamburg
  Stephan Willems

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **[---]***
- **Contact for Public Queries**

  Jakob Lueker

  Telephone: **+ 49 40 7410**
  Fax: **[---]***
  E-mail: **jlueker at uke.de**
  URL: **[---]***
- **Collaborator, Other Address**

  St. Jude Medical

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

Sources of Monetary or Material Support

- **[---]***

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

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

Status

- Recruitment Status: **Recruiting ongoing**

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: 2014/02/23

* *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.*