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

Trial Description

Title

Function of the left atrium after interventional closure of the left atrial appendage

Trial Acronym

LAA Closure - Hemodynamic Study

URL of the trial

[---]*

Brief Summary in Lay Language

The interventional closure of the left atrial appendage, which is thought to be a potential source of blood clots in patients with atrial fibrillation, has become a new alternative therapeutic strategy to oral anticoagulation. One of the regulating mechanisms to volume overload is the neurohumoral response. A strech of the atrial wall causes a secretion of natriuretic peptides, which are stored in large quantities in the walls of the left atrial appendage. The exclusion of the left atrial appendage from the systemic circulation may result in a reduced systemic response to hemodynamic changes. The aim of this study is to investigate potential changes of the neuroendocrine response after interventional atrial appendage closure.

Brief Summary in Scientific Language

Patients with atrial fibrillation have an increased risk of stroke compared to general population. Intracardiac thrombi in patients with non-valvular atrial fibrillation has been found in approximately 90% of cases in the left atrial appendage. The percutaneous, interventional closure of the left atrial appendage has become a new, alternative treatment strategy for patients with atrial fibrillation and a contraindication to oral anticoagulation.
In the PROTECT AF study patients with non-valvular atrial fibrillation were randomized at a ratio of 2 to 1 either the interventional LAA closure with the Watchman occluder or the conventional anticoagulation with Warfarin.
The study's primary endpoint was freedom of stroke, cardiovascular death and systemic embolism. Safety endpoints were significant bleeding, pericardial effusion and occluder dislocation.
The most recently published follow up data from this study showed a significantly reduced all-cause mortality and cardiovascular mortality in the interventional group with equalized safety endpoints.
The volume of the left atrial appendage makes up to one third of the left atrium. The contribution of the atrial appendage contraction to the cardiac pump function is low or negligible. The importance of the left atrial appendage is thought to be the perception of the left ventricular end diastolic pressure and the systemic response to deviations from the normal conditions. This is done via the secretion

of atrial natriuretic peptide (ANP) and brain natriuretic peptide (BNP), which are synthetized and stored in large quantities in the walls of the left atrial appendage. The secretion of ANP and BNP depends on the haemodynamic state; changes of the volume load lead to strech of the walls of the left atrium and left atrial appendage. Tabata described that the increase of the plasma levels of ANP correlated with the strech of the wall of the left atrial appendage. The exclusion of the left atrial appendage from the systemic circulation after interventional atrial appendage closure could result in a reduced systemic response to hemodynamic changes. The aim of our study is to investigate potential changes in the neuroendocrine response and its clinical significance after interventional atrial appendage closure.

Organizational Data

- DRKS-ID: **DRKS00010768**
- Date of Registration in DRKS: **2016/07/07**
- 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.: **10/15 , Ethikkommission der Medizinischen Fakultät der Otto-von-Guericke-Universität Magdeburg**

Secondary IDs

Health condition or Problem studied

- ICD10: **I48.1 - [generalization I48: Atrial fibrillation and flutter]**

Interventions/Observational Groups

- Arm 1: **Patients with an indication for an interventional atrial appendage closure and successful procedure are involved in our study after giving their informed consent. Patients undergo an Evaluation including Determination of ANP/BNP and Routine laboratory Tests as well as thransthoracic and transesophageal echocardiography and 6 min Walk Test before the procedure, 45 days and 6 months thereafter.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Single arm study**

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): **No**

Primary Outcome

Primary Outcome measure is the proof of a significant Change in the neurohumoral Response to hemodynamic overload after successful closure of the left atrial appendage

Secondary Outcome

Thrombogenesis and position of the atrial appendage closure device in the transesophageal echocardiography 45 days and 6 months after the Implantation prozedure.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Klinik für Kardiologie und Angiologie, Magdeburg**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/05/04**
- Target Sample Size: **150**
- 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

Age over 18 years; both gender; all ethnic Groups; Weight: no Limitation; women: excluded pregnancy; procedure: successful interventional closure of the left atrial appendage.

Exclusion criteria

Patients with known coronary heart disease or instable angina pectoris, severe valvular heart disease, severe diastolic dysfunction, severe pulmonary hypertension, anaemia, acute infection with fever and increase of C reactive protein and/or leukocytosis, isolated leukocytosis, increased C reactive protein, severe renal or liver insufficiency, neoplasia, pregnancy

Addresses

- **Primary Sponsor**

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  Leipziger Str. 44
  39120 Magdeburg
  Germany

  Telephone: **[---]***
  Fax: **[---]***
  E-mail: **[---]***
  URL: **www.med.uni-magdeburg.de**

- **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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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.*