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

Trial Description

Title

Impact of the use of ultrasound contrast agent on the detection of thrombi in the left atrial appendage during transesophageal echocardiography (CONDOR)

Trial Acronym

CONDOR

URL of the trial

[---]*

Brief Summary in Lay Language

[---]*

Brief Summary in Scientific Language

Atrial fibrillation (AF) is the most common rhythm disorder in adults and is associated with the risk of thrombembolic events like stroke. This is caused by the fact that in AF the reduced blood flow in the left atrium favors the formation of thrombi. In more than 90% of cases these thrombi originate from the left atrail appendage (LAA). To optimize the treatment of patients with AF it is important to know frequently wheter or not such thrombi have already been formed. The standard diagnostic approach is to use transesophageal echocardiography (TOE) to rule out LAA thrombi. However, diagnostic accuracy is limited due to echo artefacts or reduced image quality. In a relevant number of cases, theraputic procedures like electrocardioversion (ECV) or left atrial appendage closure (LAAC) have to be postponed or cancelled because of suspection of thrombi which in some cases might be based on artefacts. The use of ultrasound contrast agent which is standard of care in many other clinical scenarios like stress echocardiography could probably increase the diagnostic yield of TOE. Additionally, it could help to determine the correct size of the LAA which would improve preplanning of the LAAC procedures. Therefore, the aim of this study is to investigate whether the routine use of echo contrast agent during TOE might have an impact on the detection of thrombi in the LAA and on the determination of the size of the LAA.

Organizational Data

- DRKS-ID: **DRKS00011716**
- Date of Registration in DRKS: **2017/02/23**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***

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Date of Registration in DRKS: **2017/02/23**
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- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **22862/2016/131 , Ethikkommission der Landesärztekammer Thüringen**

Secondary IDs

Health condition or Problem studied

- ICD10: **I48 - Atrial fibrillation and flutter**

Interventions/Observational Groups

- Arm 1: **In patients with atrial fibrillation and the clinical indication for a TOE the TOE will first be performed without the use of echo contrast agent and the existence of thrombi in the LAA will be evaluated ("Thrombi yes / no / uncertain"); afterwards (during the same TOE examination) an echo contrast agent will be administered and the evaluation will be repeated ("Thrombi yes / no / uncertain")**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Non-randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Other**
- Purpose: **Diagnostic**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **No**

Primary Outcome

frequency of detected thrombi in the LAA by transesophageal echocardiography in dependance of the use of echo contrast agent (with contrast agent /wo contrast agent)

Secondary Outcome

size of the LAA ostium (minimal/ mean/ maximal diameter) with and without contrast agent

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Katholisches Krankenhaus, Erfurt**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2017/01/01**
- Target Sample Size: **100**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

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

Additional Inclusion Criteria

age > 18 years; documented atrial fibrillation (paroxysmal or persistent or permanent); clinical indication for TOE because of scheduled cardioversion or LAA closure; signed informed consent

Exclusion criteria

history of LAA closure (either interventional or surgical); allergy against SonoVue; intracardiac shunt, severe pulmonary hypertension, uncontrolled arterial

hypertension, acute respiratory distress syndrome

Addresses

- **Primary Sponsor**

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Sources of Monetary or Material Support

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

  Katholisches Krankenhaus "St. Johann Nepomuk" Erfurt
  Haarbergstr. 72

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URL: **[---]***

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

Boston Scientific
Daniel-Goldbach-Str. 17-27
40880 Ratingen
Germany

Telephone: **[---]***
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.*