Trial Description

Title

Non-Invasive Electrocardiographic Imaging of Atrial Fibrosis Substrate in Patients with persistent Atrial Fibrillation

Trial Acronym

AF-SUBSTRAT-MAP-study

URL of the trial

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Brief Summary in Lay Language

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Brief Summary in Scientific Language

Atrial fibrosis constitutes the pathophysiological substrate for development and maintenance of persistent atrial fibrillation (AF). Recent studies have revealed high arrhythmia recurrence rates after pulmonary vein isolation in patients with persistent AF and atrial fibrosis (detected as low voltage areas (LVA) on invasive catheter mapping or presence of delayed enhancement areas at MRI). It is therefore of high clinical value, to differentiate between patients with and without atrial fibrosis prior to AF ablation procedure. The aim of the current study is to evaluate the ability of the non-invasive ECG-Imaging by using an electrode vest including 252 electrodes of the “CardioInsight” system to identify extent and anatomical distribution of atrial fibrosis areas.
Although the detection of atrial fibrosis has been shown using delayed enhancement at MRI (DEMRI), this method needs confirmation by other groups, as with current MRI resolution (1-2mm) it is difficult to image atrial walls measuring 1-3mm and differentiate between myocardial areas with vs without fibrosis. We use MRI to detect loss of wall thickness and fat deposition and compare these regions to the extent and distribution of LVA both at catheter mapping and on non-invasive ECG-Imaging.

Principal Aim: Assessment of the ability/feasibility to identify the distribution and extent of atrial fibrosis by non-invasive high-resolution ECGI in patients with persistent AF. Comparison of atrial fibrosis areas on ECGI with invasive atrial voltage maps (derived routinely during the AF ablation procedure) and loss of wall thickness and fat deposition at MRI.

Organizational Data

- DRKS-ID: **DRKS00014687**
- Date of Registration in DRKS: **2018/10/22**

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- 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.: **200/18 (MPG §23b) , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

Health condition or Problem studied

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

Interventions/Observational Groups

- Arm 1: **Patients admitted for first ablation therapy of symptomatic persistent AF (atrial fibrillation) are eligible for inclusion in the study.**
  1-30 days prior to ablation (if there are no contraindications): MRI to detect loss of wall thickness and fat deposition.
  One day prior to invasive cardiac mapping and ablation procedure, eligible patients will undergo standard 12-lead ECG, TTE (transthoracic echocardiography), high-density non-invasive atrial mapping by ECGI (ElectroCardioGraphic Imaging) using 252 electrodes, followed by low-dose, non-contrast cardiac CT-scan (routine preprocedural imaging prior to AF ablation procedures) for assessment of relationship of ECGI electrodes to cardiac structures. On the following day, the biatrial voltage map will be acquired during sinus rhythm using the spiral-like mapping catheter, followed by the AF ablation procedure (PVI and ablation of atrial arrhythmias), intraprocedural TEE (transesophageal echocardiography) to rule out an left atrial thrombus, TTE to rule out an pericardial effusion after the procedure.
  After 6 and 12 months: 24-72 hour holter recordings to rule out an arrhythmia recurrence.

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Single arm study**

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- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Diagnostic**
- Assignment: **Single (group)**
- Phase: **IV**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

- Spatial correlation between the distribution and extent of LVA (low voltage areas) and atrial regions of slow electrical conduction (due to increase fibrosis) on ECGI-Maps (the day before the procedure) and invasive atrial voltage maps (during the ablation)

Secondary Outcome

- Spatial correlation between the distribution and extent of LVA and atrial regions of slow electrical conduction (due to increase fibrosis) on ECGI-Maps (the day before ablation) and loss of wall thickness and fat deposition at MRI (1-30 days before ablation).
- Predictive value of the extent of atrial low voltage substrate (assessed by ECGI vs invasive voltage mapping vs loss of wall thickness and fat deposition at MRI) on arrhythmia recurrence rate 12 months after the AF ablation. Arrhythmia recurrence is defined as AF or atrial tachycardia lasting > 30 seconds in 24-72 hour holter recordings at 6 and 12 months follow-up after the AF ablation procedure.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Universitäts-Herzzentrum Freiburg-Bad Krozingen, Bad Krozingen**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2018/11/05**
- Target Sample Size: **40**
- 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 age more or equal to 18 years for both sexes
- First catheter ablation procedure for symptomatic persistent AF
- Given and signed consent by the patient to participate to this study

Exclusion criteria

- Paroxysmal or long persistent AF
- Pregnancy
- Specific exclusion criteria for MRI (Patients with following criteria will not undergo MRI, but can be included in the study for ECG-Imaging and catheter mapping of atrial Low Voltage Areas): Implanted Cardiac Devices (Pacemaker, ICD), Claustrophobia

Addresses

- **Primary Sponsor**

  Universitäts-Herzzentrum Freiburg-Bad Krozingen - Klinik für Kardiologie und Angiologie II
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  79189 Bad Krozingen
  Germany

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

- **Contact for Scientific Queries**

Contact for Scientific Queries

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Sources of Monetary or Material Support

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

Medtronic International Trading Sàrl
Route du Molliau 31
CH-1131 Tolochenaz
Switzerland

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

Status

- Recruitment Status: **Recruiting planned**
- 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.*