Trial Description

Title

Individualized Cryoballoon Energy pulmonary vein (PV) isolation guided by real time PV recordings
The "I C E" Trial

Trial Acronym

"I C E -T" Trial

URL of the trial

[---]*

Brief Summary in Lay Language

The novel cryoballoon Advance is associated with increased cooling capacities and therefore potential side effects. Optimal cryoballoon energy titration is unknown. The cryoballoon Advance allows real time PVI observation in >85% of PVs and offers therefore systematic cryoballoon energy titration.

Brief Summary in Scientific Language

AF ablation may be considered as primary treatment. The novel cryoballoon Advance is associated with increased cooling capacities and therefore potential side effects. Optimal cryoballoon energy titration is unknown. The cryoballoon Advance allows real time PVI observation in >85% of PVs and offers therefore systematic cryoballoon energy titration.

Organizational Data

- DRKS-ID: **DRKS00004937**
- Date of Registration in DRKS: **2013/09/11**
- 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.: **FF70/2013 , Ethikkommission der Landesärztekammer Hessen**

Secondary IDs

Health condition or Problem studied

- ICD10: **I48.10 - [generalization I48: Atrial fibrillation and flutter]**

Interventions/Observational Groups

- Arm 1: **Standard Cryballoon Pulmonary vene isolation (PVI) + 1 bonus freeze with 28 mm baloon**
- Arm 2: **Cryballoon pulmonary vene isolation (PVI) but without bonus application, if first PVI during 60 secondes with 28 mm Balloon.**

Characteristics

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

Primary Outcome

Atrial tachycardia/ atrial fibrillation Reccurrence after 1 year Follow up

Secondary Outcome

Procedural safety, procedural parameters

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Medizinische Klinik III, CCB, Frankfurt a.M.**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2013/08/26**
- Target Sample Size: **100**
- 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

symtomatic atrial fibrillation

Exclusion criteria

Contraindications for PVI, Pregnancy, Severe renal dysfunction stage III-V, Participation in another clincal trail, intracardiac thrombus

Addresses

- **Primary Sponsor**

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Sources of Monetary or Material Support

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

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Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2016/12/09**

Trial Publications, Results and other documents

- Abstract **Abstract 08.Jun.2016, Cardiostim in Nice**

** 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.*