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

Trial Description

Title

Efficacy Study on Atrial Fibrillation Percutaneous Catheter Ablation With Contact Force Support 2

Trial Acronym

EFFICAS II

URL of the trial

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Brief Summary in Lay Language

EFFICAS II proposes to test the hypothesis that treatment efficacy correlates to contact force parameters applied for pulmonary vein isolation (PVI) during AF ablation.

Brief Summary in Scientific Language

EFFICAS II is a single-arm, prospective study, where the operator will have access to contact force information and use it actively to optimize the ablation result and adapting power if necessary. The endpoint will correlate contact force parameters initially applied in PV and 3 months PV isolation status, and compare results to those of EFFICAS I.

Organizational Data

- DRKS-ID: **DRKS00007281**
- Date of Registration in DRKS: **2015/08/28**
- Date of Registration in Partner Registry or other Primary Registry: **2014/04/28**
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **[---]***
- (leading) Ethics Committee Nr.: **[---]***

Secondary IDs

- Primary Registry-ID: **NCT02131337 (ClinicalTrials.gov)**
- Sponsor-ID: **EFFICAS II Version B (Endosense)**

Health condition or Problem studied

- Free text: **Paroxysmal Atrial Fibrillation**
- ICD10: **I48.0 - [generalization I48: Atrial fibrillation and flutter]**

Interventions/Observational Groups

- Arm 1: **Other: Electrophysiology study**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Single arm study**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Uncontrolled/Single arm**
- Purpose: **Basic research/physiological study**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

- Number of pulmonary vein isolation (PVI) gaps per vein; time frame: 3 months; Number of gaps in EFFICAS 2 is lower than in EFFICAS 1 and Contact force in EFFICAS 2 has reduced variability than in EFFICAS 1. Confounding parameters such as lesion continuity will be determined for the remaining gaps in EFFICAS 2.

Secondary Outcome

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Countries of recruitment

- CZ **Czech Republic**
- DE **Germany**

Locations of Recruitment

- **Asklepios St Georg, Hamburg**

Recruitment

- Planned/Actual: **[---]***
- (Anticipated or Actual) Date of First Enrollment: **2010/12/31**
- Target Sample Size: **45**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **75 Years**

Additional Inclusion Criteria

- Patient is at least 18 years of age but not over 75 years of age

- Patient has at least one episode of sustained (>30s) paroxysmal atrial fibrillation documented by 12-lead ECG, holter monitor, transtelephonic event monitor, telemetry strip, or Pacemaker respectively implantable cardioverter defibrillator (ICD) within 12 months prior to enrolment

- Patient has symptomatic paroxysmal atrial fibrillation (PAF) refractory or intolerant to at least one Class I-IV anti-arrhythmic drug

- Patient is willing and capable of complying with the study protocol requirements, including the specified follow-up scheme

- Patient provides written informed consent prior to enrolment in the study

Exclusion criteria

- Not adhering to inclusion criteria

- Active systemic infection

- Recent (within 3 months) cardiac events including myocardial infarction, acute coronary syndrome, percutaneous coronary intervention (PCI), or valve or coronary bypass grafting surgery

- Reversible causes of Arrhythmia including thyroid disorders, acute alcohol intoxication, recent (less than 3 months) major surgical procedures

- Patient has a left atrial diameter > 5.0 cm

- Patient has persistent or long-standing persistent atrial fibrillation (AF)

- Left ventricular ejection fraction < 35%

- New York Heart Association (NYHA) class III or IV

- Previous left atrial heart ablation procedure, either surgical or catheter ablation

- Patient has an intracardiac mural thrombus or has had a ventriculotomy or atriotomy

- Patient has moderate or severe structural heart disease as demonstrated by transthoracic or trans-esophageal echocardiogram of all four chambers of the heart (ventricular dysfunction or valve disease)

- Tricuspid or mitral valve replacement or repair

- If female of childbearing potential - pregnant or breastfeeding

- Patient has a bleeding diathesis or suspected pro-coagulant state

- Patient has contraindication to long-term antithromboembolic therapy (e. g. acetylsalicylic acid, heparin, warfarin)

- Presence of condition that precludes appropriate vascular access

- Heart disease in which corrective surgery is anticipated within 6 months

- Renal failure requiring dialysis

- Patient has a known sensitivity to contrast media (if needed during the procedure) that cannot adequately be controlled with pre-medication (or totally excluded)

- Patient has other anatomic or co-morbid conditions that, in the

Investigator's opinion, could limit the patient's ability to participate in the study or to comply with follow-up requirements, or impact the scientific soundness of the study results

- **Patient is currently participating in another clinical trial**
- **Patient is unlikely to survive over one year**

Addresses

■ **Primary Sponsor**

Endosense

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 complete, follow-up complete**

■ Study Closing (LPLV): **2011/10/01**

Trial Publications, Results and other documents

Deutsches Register Klinischer Studien
German Clinical Trials Register

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: 2014/11/05

** 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.*