Trial Description

Title

Multi-Centre Trial to Evaluate the Clinical Performance of the Lifetech/Medtronic Ceraflex-ASD-Occluder for Transcatheter Closure of Secundum Atrial Septal Defects

Trial Acronym

Ceraflex-ASD-Occluder

URL of the trial

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Brief Summary in Lay Language

Clinical trial in several german hospitals to confirm the efficacy of the Ceraflex-Occluder ("umbrella") for the closure of atrial septal defects.

Brief Summary in Scientific Language

The Ceraflex ASD occluder is newly introduced to the Western European Market, published data are very limited. The objective is to assess the clinical performance of the Lifetech/Medtronic Ceraflex-ASD-Occluder for Transcatheter Closure of Secundum Atrial Septal Defects (ASD II) in a standard of care setting.

Organizational Data

- DRKS-ID: **DRKS00010233**
- Date of Registration in DRKS: **2016/04/11**
- 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.: **451/15s , Ethik-Kommission der Fakultät für Medizin der Technischen Universität München**

Secondary IDs

Health condition or Problem studied

- ICD10: **Q21.1 - Atrial septal defect**

Interventions/Observational Groups

- Arm 1: **Monitoring of patients with scheduled transcatheter closure of Secundum Atrial Septal Defects (ASD II) with Ceraflex-ASD-Occluder**

Characteristics

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

Primary Outcome

Early performance success, defined as the rate of a successful placement of the device and successful closure of the defect without major complication until the day of discharge.

Secondary Outcome

Late performance success defined as: successful closure of the defect without major complication (surgical reintervention, device embolization, moderate or large residual shunt, new AV block II or III°) 6 month after the procedure

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- other **Deutsches Herzzentrum München, München**
- Medical Center **Herzzentrum Leipzig, Klinik für Kinderkardiologie, Leipzig**

- University Medical Center **Klinik für angeborene Herzfehler und Pädiatrische Kardiologie, Freiburg-Bad Krozingen**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2016/04/26**
- Target Sample Size: **100**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

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

Additional Inclusion Criteria

Able to fluently speak and understand German language, existent ostium secundum atrial septal defect (ASD II), presence of a hemodynamically significant ASD II (right ventricular volume overload determined by transthoracic echo (TTE)), defect hole(s) to be covered by an available Ceraflex ASD device, sufficient margin to place the device, Informed Consent prior to treatment and willing to return for the post-treatment evaluation at the implanting institution after 6 month

Exclusion criteria

presence of multiple defects which cannot adequately covered by implantation of one device, current participation in another ongoing clinical device or drug trial, recent myocardial infarction, unstable angina and decompensated congestive heart failure (CHF), active bacterial and/or viral infection, evidence of intra-cardiac thrombi on echocardiography, any existent disorder that, in opinion of the investigator, might interfere with the conduct of the trial

Addresses

- **Primary Sponsor**

  Deutsches Herzzentrum München
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  80636 München
  Germany

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■ **Contact for Scientific Queries**

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■ **Collaborator, Other Address**

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Sources of Monetary or Material Support

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

Lifetech Scientific (ShenZhen) Co., Ltd
Cybio Electronic Building, Langshan 2nd street
518057 Nanshan District, Shenzhen
China

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

Status

- Recruitment Status: **Recruiting complete, follow-up continuing**
- 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.*