Trial Description

Title

Open-Label Post-Marketing Surveillance Study to access safety and efficacy of the “BeGraft Coronary Stent Graft System”

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

Open-Label Post-Marketing Surveillance Study to access safety and efficacy of the “BeGraft Coronary Stent Graft System” in the treatment of acute ruptures and perforations as well as aneurysma.

Brief Summary in Scientific Language

Open-Label Post-Marketing Surveillance Study to access safety and efficacy of the “BeGraft Coronary Stent Graft System” in the treatment of acute ruptures and perforations as well as aneurysma.

Do you plan to share individual participant data with other researchers?

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00004540**
- Date of Registration in DRKS: **2012/11/29**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**

DRKS-ID: **DRKS00004540**
Date of Registration in DRKS: **2012/11/29**
Date of Registration in Partner Registry or other Primary Registry: **[---]***
Investigator Sponsored/Initiated Trial (IST/IIT): **no**

- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **5533/12 , Ethik-Kommission der Fakultät für Medizin der Technischen Universität München**

Secondary IDs

Health condition or Problem studied

- ICD10: **I20-I25 - Ischaemic heart diseases**

Interventions/Observational Groups

- Arm 1: **BeGraft Coronary Stent Graft System**

Characteristics

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

Primary Outcome

30 Day Occurrence of MACE:
• Death

- **Post procedural target vessel related Q-Wave Myocardial Infarction**
- **Emergency CABG**
- **Stent Thrombosis**

Secondary Outcome

Acute Performance Endpoints:
- **Successful sealing of acute perforation or rupture of coronary arteries**
- **Successful treatment of aneurysm of coronary arteries or coronary bypass-vein graft**
- **Patency (angiographic/visual check);**

Angiographic Endpoints at 6-8 Months:
- **Binary in-segment restenosis**
- **Binary In-stent restenosis**
- **In-stent late lumen loss;**

Clinical Endpoints at 12 Months:
- **Death**
- **MI**
- **Stent Thrombosis**
- **Target lesion revascularization at 12 months**

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Deutsches Herzzentrum München, München**
- University Medical Center **Universitätsklinikum Würzburg, Würzburg**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2013/02/08**
- Target Sample Size: **30**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **99 Years**

Additional Inclusion Criteria

1. Patients with acute perforation or rupture of coronary arteries, or
2. Aneurysm of coronary arteries or coronary bypass-vein graft and
3. Written, informed consent by the patient or her/his legally-authorized representative for participation in the study

Exclusion criteria

1. Age < 18 years
2. Patients with hemorrhagic diathesis or other disorders in which the application of anticoagulant or antiplatelet therapy is contraindicated and patients unable or unwilling to tolerate anticoagulant / antiplatelet therapy (e.g. septic ulceration, cerebrovascular complications).
3. Patients with known allergies to the used materials: stent material (L605) and/or to the graft material PTFE and/or delivery system (stainless steel) material.
4. Severe allergic reaction to the contrast medium and/or the necessary pharmaceutical treatment (e.g. aspirin) or bleeding complications.
5. Previous enrollment in this trial.
6. Patient’s inability to fully comply with the study protocol.

Addresses

- **Primary Sponsor**

  Firma Bentley InnoMed GmbH
  Lotzenäckerstr. 25
  72379 Hechingen
  Germany

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

- **Contact for Scientific Queries**

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- **Contact for Public Queries**

Contact for Public Queries

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Sources of Monetary or Material Support

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

Firma Bentley InnoMed GmbH
Lotzenäcker 25
72379 Hechingen
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.*