PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Post-Market Clinical Follow-Up (PMCF) Study Plan - BeGraft Aortic Stent Graft System

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

The clinical results obtained in the study should confirm the data regarding the safety and performance of the BGA in long-term. Residual known and unknown risks related to the “regular clinical use” of the BGA should be recognized, documented and evaluated within the PMCF study.

Brief Summary in Scientific Language

The PMCF is cunducted to confirm the performance of the device and investigate potential residual risks associated with the use of the device and to update the clinical evaluation of the device in order to ensure the long-term safety and performance of the BGA after its placing on the market.
Using the collected data it should be shown, that the implantation of the BGA statistically significant improves patient status in more than 90 % of the patients of the whole study population (primary hypothesis).

Organizational Data

- DRKS-ID: **DRKS00013959**
- Date of Registration in DRKS: **2018/02/08**
- 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.: **339/17 S , Ethik-Kommission der Fakultät für Medizin der Technischen Universität München**

Secondary IDs

Health condition or Problem studied

- ICD10: **Q28 - Other congenital malformations of circulatory system**
- ICD10: **Q25.1 - Coarctation of aorta**
- Free text: **Aortic stenosis**

Interventions/Observational Groups

- Arm 1: **Data regarding the safety and clinical success will be collected from study patients who receive the BeGraft Aoric stent during a planned intervention.**
  Therefore, on the one hand adverse events and complication will be recorded. On the other hand the vessel diameter, patency and blood pressure, before and after the implantation will be compared. Furthermore, data of the routine follow up at about 1, 6 and 12 month after the implantation will be recorded.

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- 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): **No**

Primary Outcome

Comparison of aortic/iliac diameter, pre and post stent implantation (dilatation of the narrowest segment of the coarctation by more than 50%).
Data will be assessed by angiographic or echography examinations.

Secondary Outcome

Device-related, access site-related and target site-related procedural complications will be recorded by physical examination and echography. Duration

of the assessment starts with the procedure and ends 12 month after stent implantation.

Countries of recruitment

- BE **Belgium**
- DE **Germany**
- IT **Italy**
- SE **Sweden**
- CL **Chile**
- IL **Israel**

Locations of Recruitment

- University Medical Center **Cliniques Universitaires Saint-Luc, Brüssel**
- University Medical Center **RWTH Aachen, Aachen**
- University Medical Center **Skåne University Hospital, Lund**
- Medical Center **Deutsches Herzzentrum (DHM), München**
- Medical Center **AOU San Giovanni Battista di Torino, Turin**
- University Medical Center **Universität-Herzzentrum Freiburg, Bad Krozingen**
- Medical Center **Deutsches Herzzentrum Berlin, Berlin**
- University Medical Center **Universitätsklinikum Regensburg, Regensburg**
- Medical Center **Hospital de Ninos Roberto del Río, Santiago**
- Medical Center **Schneider Children's Medical Center Israel, Petach Tikva**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2016/11/17**
- Target Sample Size: **70**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

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

Gender: **Both, male and female**

Minimum Age: **no minimum age**

Maximum Age: **no maximum age**

Additional Inclusion Criteria

The “BeGraft Aortic Stent Graft System” is indicated for - the implantation in the native and/or recurrent coarctation of the aorta (CoA*) on adolescent or adult patients with the following clinical conditions:
-- Stenosis of the aorta resulting in significant anatomic narrowing as determined by angiography or noninvasive imaging, i.e. echocardiography, magnetic resonance imaging (MRI), CT scan;
-- Stenosis of the aorta resulting in hemodynamic alterations, resulting in systolic pressure gradient, systemic hypertension or altered left ventricular function;
-- Stenosis of the aorta where balloon angioplasty is ineffective or contraindicated;
-- Stenosis diameter <20% of the adjacent vessel diameter. Stenosis that would present increased risk of vascular damage of disruption.
- and furthermore for restoring and improving the patency of the iliac arteries.

Exclusion criteria

1. When PTA is technically not possible (e. g. not feasible to access the lesion with guide wire or balloon catheter)
2. Patients too small to allow safe delivery of the Stent Graft without compromise to the systemic artery used for delivery
3. Clinical or biological signs of infection
4. Active endocarditis
5. Known allergy to aspirin, other antiplatelet agents, or heparin
6. Pregnancy
7. Aneurysms immediately adjacent to the site of Stent Graft implantation
8. Stenosis distal to the site of Stent Graft implantation
9. Lesions in or adjacent to essential collateral(s)
10. Lesions in locations subject to external compression
11. Heavily calcified lesions resistant to PTA
12. Patients with diffuse distal disease resulting in poor Stent Graft outflow
13. Patients with a history of coagulation disorders
14. Patients with aspirin allergy or bleeding complications and patients unable or unwilling to tolerate anticoagulant / antiplatelet therapy and / or non-responders to anticoagulant / antiplatelet therapy
15. Fresh thrombus formation
16. Patients with known hypersensitivity to the stent material (cobalt-chromium (L605)) and / or ePTFE

Addresses

■ **Primary Sponsor**

Bentley InnoMed GmbH
Ms. Natasa Mitrovic

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Sources of Monetary or Material Support

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

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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.*