Trial Description

Title

Physician-Initiated Trial Investigating the BeGraft Peripheral Stent Graft System as bridging stent in FEVAR for complex aortic aneurysms

Trial Acronym

BGP as bridging stent in FEVAR

URL of the trial

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Brief Summary in Lay Language

This clinical study is designed to evaluate the safety and performance of the BeGraft Peripheral (BGP) Stent Graft System as bridging stent in FEVAR procedures.

Brief Summary in Scientific Language

**The objective of this clinical investigation is to evaluate, in a controlled setting, the safety and
performance of the BeGraft Peripheral balloon expandable covered stent Graft System (Bentley
Innomed, Hechingen, Germany) implanted as bridging stent in FEVAR (fenestrated endovascular
aortic repair) for complex aortic aneurysms.**

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

No

Description IPD sharing plan

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Organizational Data

- DRKS-ID: **DRKS00023489**
- Date of Registration in DRKS: **2021/03/18**
- Date of Registration in Partner Registry or other Primary Registry: **2019/06/14**
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **20105 , Ethik-Kommission der Bayerischen Landesärztekammer**

Secondary IDs

- Primary Registry-ID: **NCT03987035 (ClinicalTrials.gov)**
- EUDAMED-No.
(for studies acc. to Medical Devices act): **CIV-20-06-033344**

Health condition or Problem studied

- ICD10: **I71.6 - Thoracoabdominal aortic aneurysm, without mention of rupture**
- ICD10: **I71.4 - Abdominal aortic aneurysm, without mention of rupture**

Interventions/Observational Groups

- Arm 1: **Application of BeGraft Peripheral Stent Graft System as bridging stent in Fenestrated Endovascular Repair (FEVAR) for complex aortic aneurysms**

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: **III**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **[---]***

Primary Outcome

1.Efficacy endpoint:
a/ Technical success defined as successfully introduction and deployment of the BeGraft Peripheral balloon expandable covered stent Graft System (Bentley Innomed, Hechingen, Germany) implanted as bridging stent in FEVAR
b / Bridging stent patency at 12 months, defined as absence of restenosis (≥50% stenosis) or sole target vessel occlusion based on CT Angio at 12 months

2. Safety endpoint at 12 months: Absence of procedure related complications and bridging
stent related endoleaks at 12 months.

Secondary Outcome

1. Bridging stent patency post-op and at 6-, 12- and 24-months, defined as absence of
restenosis (≥50% stenosis) or sole target vessel occlusion based on Duplex ultrasound or
CT Angio
2. Freedom from bridging stent related endoleaks post-op and at 6-, 12- and 24-months
3. Freedom from bridging stent related secondary intervention
4. Freedom from type I & III endoleaks post procedure and at 6, 12 and 24-months
5. 30-day mortality
6. Freedom from stent graft migration (more than 10 mm)
7. Freedom from AAA diameter increase, defined as more than 5 mm increase in maximum
diameter measured at 6- , 12- and 24- months as compared to postop-implantation
8. Freedom from aneurysm related secondary endovascular procedures
9. Freedom from conversion to open surgical repair post procedure and at 6- , 12- and 24-
months
10. Freedom from aneurysm related mortality post procedure and at 6- , 12- and 24-
months
11. Freedom from aneurysm rupture within 12- and 24-months post-implantation
12. Freedom from any major adverse events post procedural and at 6- , 12- and 24- months
13. Health Related Quality of Life scores at 12- and 24-months post implantation.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **St. Franziskus Hospital, Gefäßchirurgie, Münster**
- University Medical Center **LMU Klinikum, Gefäßchirurgie, München**
- Medical Center **Klinikum Nürnberg Süd, Gefäßchirurgie, Nürnberg**
- University Medical Center **Gefäßchirurgie, Regenburg**
- University Medical Center **Uniklinik RWTH Aachen, Gefäßchirurgie, Aachen**
- Medical Center **Klinikum Stuttgart, Stuttgart**
- University Medical Center **Gefäßchirurgie, Gießen**
- University Medical Center **UKE, Herz- und Gefäßzentrum, Hamburg**
- University Medical Center **Universitäts-Herzzentrum, Klinik für Herz- und Gefäßchirurgie, Freiburg im Breisgau**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2021/03/18**
- Target Sample Size: **100**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **56 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

**• Patient eligible for elective repair of AAA/TAAA extent IV with FEVAR in accordance with
the applicable guidelines for vascular interventions (Aneurysm size 5,5cm or aneurysm
growth of >5mm within 6 months or 1cm within 1 year).
• Patient is willing to comply with specified follow-up evaluations at the specified times
• Patient is >55 years old
• Patient understands the nature of the procedure and provides written informed consent,
prior to enrolment in the trial
• Patient has a projected life-expectancy of at least 12-months
• Patient needs to have a landing zone in their target vessel of at least 10 mm, and
coverage/ wall adaptation of the BGP should be obtained for at least 10 mm.
• No early important division branch from the target vessel with risk of coverage
• The femoral access vessel should be minimally 6-7 mm in diameter, so it can fit an 18-22 F
sheath.
• The optional axillary access vessel for introduction of the sheath through which the BGP will be advanced should be at least 2.5mm (it should be able to fit a 7F sheath)
• Absence of dissection
• Target vessels (renal arteries, superior mesenteric artery and celiac trunk) should have a diameter between 5 and 10mm
• Patient eligible for fenestrated endovascular repair as per IFU of the fenestrated endograft
• Angulation of the aorta at the level of the target vessels <45 degrees
• The fenestrated endograft has to be constructed so the fenestrations lie in front of the orifice of the target vessel, and the gap between the fenestration and the orifice of the
target vessel should not exceed 10 mm.**

Exclusion criteria

• Previously implanted stent in the target vessel
• Patients refusing treatment
• Patients for whom antiplatelet therapy, anticoagulants or thrombolytic drugs are contraindicated
• Patients with uncorrected bleeding disorders or heparin induced thrombocytopenia
• Female patient with childbearing potential not taking adequate contraceptives or
currently breastfeeding
• Any planned surgical intervention/procedure within 30 days of the trial procedure
• Patients with rupture or any patient considered to be hemodynamically unstable at onset
of procedure
• Patient is currently participating in another investigational drug or device trial that has
not completed the entire follow up period.
• Patients with diffuse distal disease resulting in poor stent outflow
• Fresh thrombus formation
• Stenosed (>50%) or occluded target vessel
• Angulation between renal artery and aortic wall <30 degrees
• Patients with known hypersensitivity to the stent material (L605) and/or PTFE
• Hybrid Approach
• Patients with a connective tissue disorder
• Patients with mycotic or inflammatory aneurysm
• Myocardial infarction or stroke within 3 months prior to the procedure
• Patients with an unstable angina pectoris or heart insufficiency NYHA 3 or 4
• Patients with ASA classification 5 or higher
• Contraindications against contrast enhanced angiography (a.e. massive hyperthyroidism)
• Patients with increased risk of intraoperative rupture
• Patients with access vessel which are too tortuous, narrow or any kind of reason that
would lead to failure of introducing and advancing an introducer sheath

Addresses

■ **Primary Sponsor**

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Sources of Monetary or Material Support

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

Bentley InnoMed GmbH
Lotzenäcker 3
72379 Hechingen
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Telephone: **[---]***
Fax: **[---]***
E-mail: **CA_Projects at bentley.global**
URL: **http://www.bentley.global**

Status

- Recruitment Status: **Recruiting ongoing**
- Reason, if "Recruitment stopped after recruiting started" or "Recruiting withdrawn before recruting started": **[---]***
- Reason, if Reason for Recruiting Stop "Other": **[---]***
- Study Closing (LPLV): **[---]***
- Number of Participants in Germany after Recruiting complete: **[---]***
- Total Number of Participants (all Sites worldwide) after Recruiting complete: **[---]***

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.*