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

Trial Description

Title

Post Market Clinical Follow-Up Study of the Derivo® Embolisation Device

Trial Acronym

Derivo

URL of the trial

[---]*

Brief Summary in Lay Language

Within the trial "Post Market Clinicl Follow-up of the Derivo Embolisation Device" the treatment of intracranial aneurysms (= diliatation of brain vessels) will be assessed. The treatment with the above mentioned Flow-Diverter will be performed within the intended use of the device.

Brief Summary in Scientific Language

A recent metaanalysis published by Brinjikji including 29 studies and 1451 patients with 1654 aneurysms treated by FD reported a procedure-related morbidity and mortality of 5% and 4% respectively. The rate of post-operative subarachnoid and intraparenchymal hemorrhage were 3% each with significantly lower odds of perforator infarction among patients with anterior circulation aneurysms compared with those with posterior circulation aneurysms. The authors conclude that treatment of intracranial aneurysms with FD is feasible and effective with high complete occlusion rates. However they consider the risk of procedure-related morbidity and mortality non negligible (Brinjikji W1, Murad MH, Lanzino G, Cloft HJ, Kallmes DF. Endovascular treatment of intracranial aneurysms with flow diverters: a meta-analysis. Stroke. 2013 Feb;44(2):442-7.). The study objective is to examine the safety and efficacy of aneurysm treatment with the Derivo flow-diverter with respect to the mid- and long-term clinical and angiographic outcomes.

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

No

Description IPD sharing plan

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Organizational Data

- DRKS-ID: **DRKS00006103**
- Date of Registration in DRKS: **2014/10/08**
- 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.: **190/14 (§ 23b MPG) , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

Secondary IDs

Health condition or Problem studied

- Free text: **incidental intracranial aneurysms**
- ICD10: **I67.1 - Cerebral aneurysm, nonruptured**

Interventions/Observational Groups

- Arm 1: **Treatment with Derivo Flow-Diverter**

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): **N/A**

Primary Outcome

Modified Rankin Score (mRS) at 18 months

Secondary Outcome

1) Procedural result
• Number of flow-diverters successfully deployed over aneurysm neck in relation to the number of attempted flow-diverter treatments as determined by the core-lab.
• Wall apposition of the flow-diverter(s) per patient as determined by the core-lab:
1. correct wall apposition
2. gap between FD and vessel wall <25% of vessel diameter
3. gap between FD and vessel wall >25% of vessel diameter
• Time needed for Derivo deployment.
• Initial angiographic outcome: Core-lab evaluation of final controls with respect to the scale of Szikora
• In those patients were additional coils are being used for aneurysm treatment the Montreal classification will apply for determining the treatment result in addition to the Szikora classification.
• Procedural complication rate of aneurysm treatment

2) Post-procedural result
• Number of new neurological deficits immediately after flow-diverter implantation
• Initial clinical outcome: Comparison between initial Modified Ranking Scale (mRs) and mRs upon discharge. In those patient that had a procedural complication with subsequent stroke National Institutes of Health Stroke Scale (NIHSS) upon discharge.
• Midterm (3-6 months) clinical outcome: mRs
• Midterm (3-6 months) and longterm (12-18 months) angiographic outcome: Core-lab evaluation of mid-term angiographies with respect to the classification of Kamran Grading
• In those patients were additional coils are being used for aneurysm treatment the Montreal classification will apply for determining the treatment result in addition to the Kamran grading system.
• Quality of Life questionnaire SF-12 before treatment, after 3-6 and 12-18 months

Countries of recruitment

- DE **Germany**
- PL **Poland**

Locations of Recruitment

- University Medical Center **Universitätsklinikum Freiburg - Klinik für Neuroradiologie, Freiburg im Breisgau**
- Medical Center **Alfried Krupp Krankenhaus - Klinik f. Radiologie u. Neuroradiologie, Essen**
- University Medical Center **Universitätsklinikum des Saarlandes Klinik f. Diagnostische u. Interventionelle Neuroradiologie, Homburg**

- Medical Center **John Paul II Western Hospital, Grodzisk Mazowiecki**
- University Medical Center **Universitätsklinikum Magdeburg - Institut für Neuroradiologie, Magdeburg**
- University Medical Center **Universitätsklinikum Würzburg - Abteilung für Neuroradiologie, Würzburg**
- University Medical Center **Klinikum recht der Isar - TU München Kopfzentrum, München**
- Medical Center **Klinikum Dortmund - Klinik für Radiologie und Neuroradiologie, Dortmund**
- University Medical Center **Klinik und Poliklinik für Neuroradiologische Diagnostik und Intervention, Hamburg-Eppendorf**
- University Medical Center **Abteilung für Neuroradiologie, LMU München**
- University Medical Center **Institut für Diagnostische und Interventionelle Radiologie, Düsseldorf**
- Medical Center **Samodzielny Publiczny Specjalistyczny Szpital Zachodni im. Jana Pawła II, Grodzisk Mazowiecki**
- University Medical Center **Universitätsklinikum Schleswig-Holstein, Campus Kiel, Kiel**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2014/07/17**
- Target Sample Size: **100**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

1. Patients with intracranial aneurysms deemed treatable with the Derivo® flow-diverter
2. The target aneurysm cannot be treated with other endovascular techniques or there is a higher treatment risk with other endovascular or neurosurgical techniques. (= treatment within intended use)
3. The patients have read and understood the informations with respect to the study and have given their consent prior to aneurysm treatment with the Derivo® flow-diverter.
4. Modified Rankin score of 0 or 1

Exclusion criteria

1. Patients < 18 years of age
2. Patients with aneurysms related to arteriovenous malformations
3. Patients with known contraindications to antiplatelet therapy and/or anticoagulant therapy.
4. Pregnant or breast-feeding patients
5. Patients with confirmed subarachnoidal bleeding within the last two months
6. Patients likely to be unable to attend clinical and angiographic follow-up at 6 and 18 months
7. Patients with a contraindication according to the Instructions for use
- The size of the aneurysm and/or the size of the aneurysma forming vessel is not within the indicated area.
- An angiographically inappropriate vascular anatomy or vascular aberration for endovascular treatment.

Addresses

■ **Primary Sponsor**

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URL: **[---]***

■ **Contact for Scientific Queries**

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URL: **http://www.uniklinik-freiburg.de/neuroradiologie.html**

Sources of Monetary or Material Support

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

ACANDIS GmbH
Theodor-Fahrner-Str. 6
75177 Pforzheim
Germany

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

Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2019/10/25**

Trial Publications, Results and other documents

- Paper **Publikation der Derivo-Studie im Jounal of NeuroInterverntional Surgery**

** 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.*