

Trial Description

Title

GermanVasc-Registry within the IDOMENEO study

Trial Acronym

IDOMENEO

URL of the trial

<http://www.idomeneo.de>

Brief Summary in Lay Language

The government-funded registry-based IDOMENEO-study will consecutively include 10,000 patients with invasive revascularisations for symptomatic peripheral arterial disease performed at approximately 30-40 German vascular centres utilizing the GermanVasc registry system.

Brief Summary in Scientific Language

The study is a prospective non-randomized registry trial including invasive endovascular (ER) and open-surgical (OR) revascularisations of chronic symptomatic peripheral arterial disease (PAD) of the lower extremities performed in 30-40 legally endorsed multidisciplinary German hospitals. All patients matching the inclusion criteria are consecutively included for an enrolment period of six months or until 10,000 patients have been included in the study registry. There are three follow-up measures at 3 months, 6 months and 12 months. The study outcomes consist of indicators of outcome quality defined by consensual agreement among experts in the field of vascular medicine. Plausibility-checks for integrity of submitted data are implemented into the registry system and all data needs to be verified by a physician employed in the participating study centre. Furthermore, the study data will undergo an independent quality assurance for internal validity by random-sample cross-checking against local patient files.

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

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Description IPD sharing plan

[---]*

Organizational Data

■ DRKS-ID: **DRKS00014649**

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- Date of Registration in DRKS: **2018/05/07**
- Date of Registration in Partner Registry or other Primary Registry: **2017/03/31**
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **PV5691 , Ethik-Kommission der Ärztekammer Hamburg**

Secondary IDs

- Primary Registry-ID: **NCT03098290 (clinicaltrials.gov)**

Health condition or Problem studied

- ICD10: **I70.2 - Atherosclerosis of arteries of extremities**

Interventions/Observational Groups

- Arm 1: **Catheter-based endovascular revascularization**
- Arm 2: **Endarterectomy**
- Arm 3: **Bypass surgery**

Characteristics

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

Primary Outcome

Before discharge, after 3 months, after 6 months, after 12 months:

Major Adverse Cardiovascular Events (MACE)

Major Adverse Limb Events (MALE)

Myocardial Infarction

Stroke or TIA

Major Amputation

Major Reintervention

Any Reintervention

Wound Infection

Vascular Access-related Major Complication

Maximum Walking Distance

Rutherford-Classification

Ankle-Brachial-Index

Secondary Outcome

Evaluated at time of discharge, after 3 months, after 6 months, and after 12 months:

Minor Amputation

Primary Patency

Secondary Patency

Quality of Life

Healing of Wound Infections or Wound Healing Disorders

Lymphatic Fistula

Ambulation

Technical Success

Patient Satisfaction

Total Length of Hospital Stay

Functional Status

Hospital-acquired Infection

Catheter-related Infection

Ankle-Brachial-Index

Countries of recruitment

- **DE Germany**

Locations of Recruitment

- Medical Center **Universitätsklinikum Hamburg-Eppendorf, Hamburg**
- Medical Center **Agaplesion Diakonie Kliniken Kassel, Kassel**
- Medical Center **Agaplesion Diakonieklinikum Hamburg, Hamburg**
- Medical Center **Asklepios Klinik Birkenwerder, Birkenwerder**
- Medical Center **Carl-Thiem-Klinikum Cottbus, Cottbus**
- Medical Center **Charité Universitätsmedizin Berlin (Campus Benjamin Franklin), Berlin**

- Medical Center **Elisabeth-Krankenhaus Essen, Essen**
- Medical Center **Ev. Krankenhaus Mühlheim an der Ruhr, Mühlheim an der Ruhr**
- Medical Center **Frankfurter RotKreuz-Kliniken e.V., Frankfurt a.M.**
- Medical Center **Friedrich-Ebert-Krankenhaus Neumünster, Neumünster**
- Medical Center **Gemeinschaftskrankenhaus Bonn (Haus St. Petrus), Bonn**
- Medical Center **GFO Kliniken Bonn (Betriebsstätte St. Marien), Bonn**
- Medical Center **Helios Klinikum Berlin-Buch, Berlin**
- Medical Center **Helios Klinikum Erfurt, Erfurt**
- Medical Center **Herz- und Gefäßzentrum Bad Bevensen, Bad Bevensen**
- Medical Center **Isarklinikum München, München**
- Medical Center **Kath. Karl-Leisner-Klinikum I Marienhospital Kevelaer, Kevelaer**
- Medical Center **Kerckhoff-Klinik Bad Nauheim, Bad Nauheim**
- Medical Center **Klinikum Chemnitz gGmbH, Chemnitz**
- Medical Center **Klinikum Darmstadt GmbH, Darmstadt**
- Medical Center **Klinikum Magdeburg gGmbH, Magdeburg**
- Medical Center **Klinikum Mutterhaus der Borromäerinnen gGmbH (Mitte), Trier**
- Medical Center **Klinikum Rheine I Mathias Spital, Rheine**
- Medical Center **Klinikum Stadt Soest, Soest**
- Medical Center **SRH-Klinikum-Karlsbad-Langensteinbach, Karlsbad**
- Medical Center **Städtisches Klinikum Karlsruhe, Karlsruhe**
- Medical Center **Städtisches Klinikum Dresden Friedrichstadt, Dresden**
- Medical Center **Theresienkrankenhaus Mannheim, Mannheim**
- Medical Center **Universitäres Herzzentrum Hamburg GmbH, Hamburg**
- Medical Center **Universitäts-Herzzentrum Freiburg (Standort Bad Krozingen), Freiburg im Breisgau**
- Medical Center **Universitäts-Herzzentrum Freiburg (Standort Freiburg), Freiburg im Breisgau**
- Medical Center **Universitätsklinikum Jena, Jena**
- Medical Center **Universitätsklinikum Schleswig-Holstein (Campus Kiel), Kiel**
- Medical Center **Universitätsklinikum Schleswig-Holstein (Campus Lübeck), Lübeck**
- Medical Center **Zentralklinik Bad Berka GmbH, Bad Berka**

Recruitment

- Planned/Actual: **Actual**
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(Anticipated or Actual) Date of First Enrollment: **2018/05/01**

- Target Sample Size: **10000**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

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

Additional Inclusion Criteria

Invasive open-surgical (endarterectomy, bypass surgery) or catheter-based endovascular revascularizations of symptomatic peripheral arterial disease

Exclusion criteria

**No informed consent
Patient <18 years**

Addresses

■ Primary Sponsor

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■ Contact for Scientific Queries

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Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

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Status

- Recruitment Status: **Recruiting ongoing**

DRKS-ID: **DRKS00014649**

Date of Registration in DRKS: **2018/05/07**

Date of Registration in Partner Registry or other Primary Registry:
2017/03/31

- Study Closing (LPLV): [---]*

Trial Publications, Results and other documents

- Approval of ethics comm. (mandatory for transfer to Studybox) **Ethikvotum der federführenden Ethikkommission Hamburg**
- Paper **Behrendt CA, et al. IDOMENEO - Ist die Versorgungsrealität in der Gefäßmedizin Leitlinien und Versorgungsgerecht. Gefäßchirurgie 2017;22:41-47.**
- Paper **Behrendt CA, et al. Leitlinienempfehlungen in der PAVK Therapie. Bundesgesundheitsbl 2018;61:218-223.**

* 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.