## Trial Description

### Title
RECCORD (Recording Courses of Vascular Diseases) Registry

### Trial Acronym
RECCORD

### URL of the trial
https://www.reccord.de

### Brief Summary in Lay Language
Vascular Registry of Deutschen Gesellschaft für Angiologie - Gesellschaft für Gefäßmedizin e.V.

### Brief Summary in Scientific Language
The RECording COurses of vascular Diseases registry (RECCORD registry) is an observational, prospective, multicentre, all-comers registry platform. In the initial phase, patients referred for endovascular revascularization of peripheral artery disease (PAD) of the lower limbs will be prospectively included and followed up for at least one year. At baseline, data on patients' demographic characteristics, comorbidities, previous peripheral interventions, medication, and clinical stage of PAD (Rutherford category), haemodynamic parameters, and procedural data including complications will be assessed. Major adverse cardiac and limb events will be recorded at planned (at six and 12 months) and at any unplanned visits. For details see NM Malyar et al., Rationale and design of the RECording COurses of vascular Diseases registry (RECCORD registry). Vasa. https://doi.org/10.1024/0301-1526/a000631

### Do you plan to share individual participant data with other researchers?
[---]*

### Description IPD sharing plan
[---]*

## Organizational Data
- **DRKS-ID:** DRKS00013585
- **Date of Registration in DRKS:** 2018/02/23
DRKS-ID: **DRKS00013585**
Date of Registration in DRKS: **2018/02/23**

- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **17-611, Ethik-Kommission der Medizinischen Fakultät der Ludwig-Maximilians-Universität München**

### Secondary IDs

- Universal Trial Number (UTN): **U1111-1209-6562**

### Health condition or Problem studied

- **ICD10**: I70 - Atherosclerosis

### Interventions/Observational Groups

Arm 1: **Patients referred for endovascular revascularization of peripheral artery disease (PAD) of the lower limbs will be prospectively included in the registry and followed up for at least one year. At baseline, data on patients' demographic characteristics, comorbidities, previous peripheral interventions, medication, and clinical stage of PAD (Rutherford category), haemodynamic parameters, and procedural data including complications will be assessed. Major adverse cardiac and limb events will be recorded at planned (at six and 12 months) and at any unplanned visits. The RECCORD registry will provide a comprehensive dataset depicting the current real life practice and outcome of vascular care.**

### Characteristics

- **Study Type**: Non-interventional
- **Study Type Non-Interventional**: Observational study
- **Allocation**: Single arm study
- **Blinding**: [---]*
- **Who is blinded**: [---]*
- **Control**: Uncontrolled/Single arm
- **Purpose**: Other
- **Assignment**: Single (group)
Study Type: **Non-interventional**

Allocation: **Single arm study**

Control: **Uncontrolled/Single arm**

Purpose: **Other**

Phase: **N/A**

Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

**Primary Outcome**


**Secondary Outcome**

4. Quality of Life, 5. Re-Intervention

**Countries of recruitment**

- DE Germany

**Locations of Recruitment**

- Medical Center *Klinikum der Ludwig-Maximilians Universität, München*
- Medical Center *Evangelisches Krankenhaus Königin Elisabeth Herzberge gGmbH, Berlin*
- Medical Center *Sankt Gertrauden-Krankenhaus, Berlin*
- Medical Center *Klinikum Immenstadt, Immenstadt*
- Medical Center *Universitätsklinikum Münster, Münster*
- Medical Center *Universitätsklinikum Heidelberg, Heidelberg*
- Medical Center *SRH Klinikum Karlsbad-Langensteinbach, Karlsbad*
- Doctor's Practice *Berlin*
- Medical Center *Marienhospital, Brühl*
Medical Center St. Josefs-Krankenhaus, Potsdam
Medical Center Städtisches Krankenhaus Dresden / Friedrichstadt, Dresden
Medical Center Klinik Kösching, Kösching
Doctor’s Practice Mönchengladbach
Medical Center Helios Klinikum Velbert, Velbert
Medical Center Klinikum Arnsberg, Arnsberg
Doctor’s Practice Frankfurt / Oder
Medical Center Agaplesion Bethesda Krankenhaus gGmbH, Wuppertal

Recruitment

- Planned/Actual: Planned
- (Anticipated or Actual) Date of First Enrollment: 2019/02/01
- Target Sample Size: 20000
- Monocenter/Multicenter trial: Multicenter trial
- National/International: National

Inclusion Criteria

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

Additional Inclusion Criteria

- any type of endovascular interventions for symptomatic PAD
- endovascular intervention for PAD of lower extremities, i.e. below the aorto-iliac bifurcation

Exclusion criteria

- patients undergoing hybrid-(surgical and endovascular) and/or surgical interventions for symptomatic PAD
- patients with a life expectancy of <6 months
- endovascular intervention for reasons other than symptomatic PAD

Addresses

- Primary Sponsor
  Deutsche Gesellschaft für Angiologie - Gesellschaft für Gefäßmedizin e.V.
  Mr. Prof. Dr. med. Sebastian Schellong
  Schiffbauerdamm 40
Primary Sponsor

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Sources of Monetary or Material Support

Private sponsorship (foundations, study societies, etc.)

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Status

- Recruitment Status: Recruiting ongoing
- Study Closing (LPLV): [---]*

Trial Publications, Results and other documents

  Description: Rationale and design of the RECording COurses of vasculaR Diseases registry (RECCORD registry), Vasa (2017), 46, pp. 262-267