



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 RECCORDing 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 RECCORDing COurses of vasculaR Diseases registry (RECCORD registry). Vasa.

<https://doi.org/10.1024/0301-1526/a000631>

Organizational Data

- DRKS-ID: **DRKS00013585**
- Date of Registration in DRKS: **2018/02/23**
- 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.: **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)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

1. Peri- and post-interventional complications (puncture-site complications & intervention-related complications over 30 days), 2. Amputations, 3. Survival

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**

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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

- Paper URL: **http://econtent.hogrefe.com/doi/pdf/10.1024/0301-1526/a000631**
Description: Rationale and design of the REcording COurses of vasculaR Diseases registry (RECORD registry), Vasa (2017), 46, pp. 262-267

* 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.