

**Trial Description****Title**

Progress monitoring for the evaluation of complications that occur in direct or indirect connection with the compression therapy / thrombin injection to treat catheter-associated complications (pseudoaneurysm)

Trial Acronym

[---]*

URL of the trial

http:///

Brief Summary in Lay Language

The iatrogenic pseudoaneurysm (PSA) provides up to 4%, the most common complication after cardiac catheterization. The treatment spectrum includes manual and ultrasonic-assisted compression, the prolonged tourniquet system and thrombin injection and operative rehabilitation. Although these are effective and safe therapy strategies, isolated cases of thrombosis and pulmonary embolism are described with a fatal outcome. An investigation of the lower leg with respect to thrombosis, and direct comparison of the two strategies has not yet been tested. This study is a retrospective analysis of data collected of routine patient

Brief Summary in Scientific Language

The catheterization is an established procedure. Compared to surgical procedures it is less invasive and offers diagnostic possibilities and therapeutic options. Nevertheless, complications can occur here as well. Immobilization in conjunction with a pressure bandage or special closure techniques should prevent the patient for particular complications that can occur in the groin. If there are still a pseudoaneurysm or arteriovenous (AV) fistulas, they must be treated separately. In the context of diagnosis and treatment of catheter-associated complications, occurs (even independent of the study) the ultraschallgestützte examination of the leg veins. In this way can be diagnosed or ruled out eventually encountered thrombosis. The aim of the study is to find out as part of a retrospective data analysis, whether during therapy occurs a high incidence of complications, such as the occurrence of venous thrombosis. Based on this, the development of consistent therapeutic treatment strategy is planned .

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

[---]*

Description IPD sharing plan

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Organizational Data

- DRKS-ID: **DRKS00009961**
- Date of Registration in DRKS: **2016/02/01**
- Date of Registration in Partner Registry or other Primary Registry: [---]*
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **No approval required according to EC**
- (leading) Ethics Committee Nr.: [---]*, **Ethikkommission der Medizinischen Fakultät der Otto-von-Guericke-Universität Magdeburg**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1178-8089**

Health condition or Problem studied

- ICD10: **I72.4 - Aneurysm and dissection of artery of lower extremity**

Interventions/Observational Groups

- Arm 1: **Patients with the treatment strategy of conventional compression bandage, which have a PSA and thus associated thrombosis.**

The diagnosis takes place by means of color-coded duplex sonography. It will be done a venous compression ultrasonography of all veins on both upper and lower legs.

The TVT-diagnosis takes place at several points in time:

- 1. at the time with PSA Diagnostics (often, however, was already a pressure bandage on station created as the Koimplikation was äußerlich visible, which is then already considered a first therapy**
- 2. At the time of therapy**
- 3. time about 24 hours after treatment, if necessary, at the time of other therapies and after these additional about 24 hours later.**

It is a retrospective data analysis.

- Arm 2: **Patients with the treatment strategy duplex based thrombin who have a PSA and thus associated thrombosis.**

The diagnosis takes place by means of color-coded duplex sonography. It will be done a venous compression ultrasonography of all veins on both upper and



lower legs.

The TVT-diagnosis takes place at multiple time points:

- 1. at the time of PSA Diagnostics**
- 2. At the time of therapy**
- 3. time about 24 hours after treatment, if necessary, at the time of other therapies, and even after these other about 24 hours later.**

It is a retrospective data analysis.

Characteristics

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

Primary Outcome

Comparison of the effectiveness of treatment strategies conventional pressure bandage vs. duplex-based thrombin in patients with a PSA, and the analysis of the thus-associated thrombosis.

Other side effects which occurred next to the pseudoaneurysm are even AV (arteriovenous) fistulas and hematomas.

The diagnosis took place by means of color-coded duplex sonography. A venous compression ultrasonography of all veins on both upper and lower legs was performed. too.

It is a retrospective data analysis.

The catheter examinations were carried out by 2010-2015.

Secondary Outcome

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Countries of recruitment

- **DE Germany**



Locations of Recruitment

- Medical Center **Klinikum Darmstadt Zentrum für Gefäßmedizin, Darmstadt**
- Medical Center **Carl-von-Basedow-Klinikum Saalekreis GmbH, Medizinische Klinik I, Merseburg, Merseburg**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2016/01/19**
- Target Sample Size: **350**
- 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

Patients with a thrombosis-free venous System

Only the patients were included if a PSA had diagnosed and for which no DVT was detected before diagnosis or before Tourniquet system . There are analyzed retrospectively data from patients who were treated from 2010-2015.

Exclusion criteria

Patients who showed already an old or fresh thrombosis in the duplex examination with the diagnosis of PSA

Addresses

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Sources of Monetary or Material Support

■ **Institutional budget, no external funding (budget of sponsor/PI)**

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URL: [---]*

Status

- Recruitment Status: **Recruiting complete, follow-up continuing**
- Study Closing (LPLV): [---]*

Trial Publications, Results and other documents

- Abstract **Poster DGA April 2016**
- Trial results **Poster ESC 2016**
- Further trial documents **Posterpreis ESC 2016**

* 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.