PLEASE NOTE: This trial has been registered retrospectively.

Trial Description

Title

Prospective, Systematic Observational Study on the Daily Use of Cilostazol (Pletal®) in Clinical Vascular Surgical Practice - Significant Improvement of Walking Distance and Quality of Life for Patients with PAOD, Stage II b

Trial Acronym

/

URL of the trial

http://

Brief Summary in Lay Language

In the course of a clinical observation study, vascular-surgical patients with cilostazole medication were examined over a defined period with regard to the maximum walking distance, the personal assessment of the quality of life during the course of the study, the influence of secondary diseases on the walking distance and the occurrence of side effects and their influence on the treatment.

Brief Summary in Scientific Language

Through a defined time period, all consecutive vascular surgical patients with indicated and initiated medication with cilostazol (PAOD, stage II b) were registered and controlled clinically within 3-month time intervals to investigate the therapeutic effect in a representative, specifically vascular surgical group of patients using a systematic prospective, unicentre clinical observational study. In particular, maximum walking distance, subjective (semi-quantitative) assessment of the quality of life, impact of accompanying diseases as well as the occurrence of adverse effects, and their impact on the treatment were studied.

Organizational Data

- DRKS-ID: DRKS00011235
- Date of Registration in DRKS: 2016/12/21
- 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
DRKS-ID: **DRKS00011235**
Date of Registration in DRKS: **2016/12/21**
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**

der Otto-von-Guericke-Universität Magdeburg

**Secondary IDs**
- Universal Trial Number (UTN): **U1111-1188-8658**

**Health condition or Problem studied**
- **ICD10**: I70.22 - [generalization I70.2: Atherosclerosis of arteries of extremities]

**Interventions/Observational Groups**
- **Arm 1**: Observation period after initiation of cilostazole therapy with a dosage of 2 × 100 mg / day over 12 months
  - collection of the demographic master data, possible influencing companion diseases
  - documentation of drug reactions and dose adjustments of cilostazole
  - in the case of a discontinuation of cilostazole, the reason for this has been determined and documented.
  - booking for follow-up at 12-week intervals and recording of the change of primarily collected data and the change in the subjective perception of the quality of life is semiquantitative ("better-equal-worse")
  - continuing clinical examination included
    1. Skin status / lesions
    2. Muscular atrophy
    3. palpation of pulses and skin temperature of the lower extremities in the side comparison.
    4. Arterial Doppler sonography with determination of the ABI and the
    5. Determination of the maximum walking distance using standardized treadmill measurement.

**Characteristics**
- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
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): **No**

### Primary Outcome

The standardized tread determined maximum walking distance / stretch extension after 3, 6, 9 and 12 months after medication initiation

### Secondary Outcome

Determination:
- the quality of life through semiquantitative elevation of the tendency in subjective sensation,
- the influence of secondary diseases,
- the influence of parameters / factors, the ABI as a relevant therapeutic effect parameter,
- the side-effect profile,

The frequency of a dose reduction or a discontinuation of therapy as well as
- of medically relevant adjuvant therapies

All surveys were carried out after 3, 6, 9 and 12 months after medication initiation

### Countries of recruitment

- **DE Germany**

### Locations of Recruitment

- University Medical Center Universitätsklinik für Allgemein-, Viszeral- und Gefäßchirurgie, Magdeburg

### Recruitment
Planned/Actual: **Actual**

- (Anticipated or Actual) Date of First Enrollment: **2009/07/01**
- Target Sample Size: **150**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

### Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **40 Years**
- Maximum Age: **85 Years**

### Additional Inclusion Criteria

- the appropriate application of cilostazole therapy,
- anamnestic, clinical, and Doppler sonography
  (3 months' consultation - consultations over a period of at least 6 months with anamnesis survey, including investigation of painless and maximal walking distance), clinical baseline examination of vascular status, Doppler sonography of the legs with determination of the ABI),
- taking the recommended dose of cilostazole: 2 × 100 mg or 2 × 50 mg
- a basic compliance.

### Exclusion criteria

- vascular surgery or radiological interventions of the lower extremity during the administration of cilostazole
- "off label use" of Cilostazol,
- the presence of a tumor,
- severe renal impairment with a creatinine clearance <25 ml / min,
- moderate or severe hepatic impairment,
- the presence of a pregnancy,
- history of ventricular tachycardia, ventricular fibrillation, multifocal ventricular ectopia, or prolongation of the QTc interval,
- amputated limbs of the lower extremity or
- degenerative joint diseases that do not allow walking distance determination or immobility, and finally
- lack of basic compliance, especially when taking medication.

### Addresses

- **Primary Sponsor**
  Universitätsklinik für Allgemein-, Viszeral- und Gefäßchirurgie
  Mr. Prof. Dr. med. Frank Meyer
  Leipziger Str. 44
  39120 Magdeburg
  Germany
Primary Sponsor

Universitätsklinik für Allgemein-, Viszeral- und Gefäßchirurgie
Mr. Prof. Dr. med. Frank Meyer
Leipziger Str. 44
39120 Magdeburg
Germany

Telephone: +49-391-67-15682
Fax: +49-391-67290321
E-mail: frank.meyer at med.ovgu.de
URL: [---]*

Contact for Scientific Queries

Universitätsklinik Für Allgemein- Viszeral- und Gefäßchirurgie
Mr. Prof. Dr. med. Zuhir Halloul
Leipziger Str. 44
39120 Magdeburg
Germany

Telephone: +49-391-67-15666
Fax: +49-391-67-14318
E-mail: zuhir.halloul at med.ovgu.de
URL: [---]*

Contact for Public Queries

Universitätsklinik für Allgemein-, Viszeral- und Gefäßchirurgie
Mr. Prof. Dr. med. Frank Meyer
Leipziger Str. 44
39120 Magdeburg
Germany

Telephone: +49-391-67-15682
Fax: +49-391-67290321
E-mail: frank.meyer at med.ovgu.de
URL: [---]*

Sources of Monetary or Material Support

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

Universitätsklinik für Allgemein-, Viszeral- und Gefäßchirurgie
Mr. Prof. Dr. med. Frank Meyer
Leipziger Str. 44
39120 Magdeburg
Germany

Telephone: +49-391-67-15682
Institutional budget, no external funding (budget of sponsor/PI)

Universitätsklinik für Allgemein-, Viszeral- und Gefäßchirurgie
Mr. Prof. Dr. med. Frank Meyer
Leipziger Str. 44
39120 Magdeburg
Germany

Telephone: +49-391-67-15682
Fax: +49-391-67-290321
E-mail: frank.meyer at med.ovgu.de
URL: [---]*

Status

- Recruitment Status: Recruiting complete, follow-up complete
- Study Closing (LPLV): 2012/06/29

Trial Publications, Results and other documents

- Paper Originalarbeit 2015
- Paper Originalarbeit Interimsanalyse 2011

* 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.