PLEASE NOTE: *This trial has been registered retrospectively.*

Trial Description

Title

Magdeburg - Optimization of percutaneous coronary stent implantation

Trial Acronym

MD-OPCI Study

URL of the trial

[---]*

Brief Summary in Lay Language

If complex constriction (stenosis) of the coronary arteries is shown in the clarification of the suspected constriction of the coronary arteries, a balloon dilation (PTCA) and a stent implantation (insertion of a stent) may be performed in the same session.
The result of the stent implantation is checked by means of routinely performed OCT (Optical Computed Tomography) and FFR (Flow Rate Measurement).
If necessary, the implanted stent is optimized based on images obtained in the coronary vessel. The optimization of the stent is performed on the basis of clearly defined criteria. Here are basically two scenarios conceivable: 1) the already implanted stent can be expanded by a balloon to achieve an optimal size of the stent or 2) to treat the diseased coronary vessel optimal it may be necessary to implant more stents. Which strategy is pursued, is decided during the treatment based on the obtained images, according to clearly defined criteria.
In the context of the study, 12 months after treatment, a call will be made by a member of the study team to see how you are.
The study will systematically record and analyze only data collected during treatment.

Brief Summary in Scientific Language

The MD-OPCI study is a prospective observational study investigating the use of FFR (Fractional Flow Reserve)/ OCT (Optical Coherence Tomography)-guided PCI (Percutaneous Coronary Intervention) -optimisation on the final result of PCI in patients with suspected or known coronary artery disease, including acute myocardial infarction (except for ST elevation myocardial infarction), who present for coronary angiography with the expectation of proceeding to PCI.
Data from patients, age 30-90, with complex coronary lesions (ACC–AHA class B2/C) will be included in the study.
All PCI procedures, coronary imaging, FFR measurements will be performed within clinical routine and the MD-OPCI study will gather and analyse data from every single stage of the procedure. Briefly, after stenting complex lesions all patients are recommended to undergo intravascular imaging with OCT and in all patients the FFR will be assessed in the stented vessel.

In addition to routine follow-up a telephone follow-up will be performed at 12 months to assess current symptoms and cardiovascular events.

Organizational Data

- DRKS-ID: **DRKS00016566**
- Date of Registration in DRKS: **2019/02/18**
- 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.: **110/17 , Ethikkommission der Medizinischen Fakultät der Otto-von-Guericke-Universität Magdeburg**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1226-5086**

Health condition or Problem studied

- ICD10: **I20 - Angina pectoris**
- ICD10: **I21 - Acute myocardial infarction**
- ICD10: **I22 - Subsequent myocardial infarction**
- ICD10: **I23 - Certain current complications following acute myocardial infarction**
- ICD10: **I24 - Other acute ischaemic heart diseases**
- ICD10: **I25 - Chronic ischaemic heart disease**

Interventions/Observational Groups

- Arm 1: <style fontName='DejaVu Sans' isBold='true'> a total of 100 people
  - Data collected during treatment are systematically recorded and subsequently analyzed.

  The study project runs as follows:

  1. Review of inclusion and exclusion criteria

  2. Carrying out the normal cardiac catheterization
  followed by stent implantation

  3. The result of stent implantation is checked by OCT and FFR (fractional flow rate).
  4. If necessary, optimize the stent based on the previously obtained images
  The optimization of the stent is performed on the basis of clearly defined criteria. Here are basically two scenarios imaginable:

1) the already implanted stent can be inflated by a balloon to achieve an optimal size of the stent or 2) to optimally treat the diseased coronary vessel it may be necessary to implant additional stents.

For data-analysis the study population will be divided into two groups according to the post-PCI FFR recording; Group A and B.
Group A includes patients with an FFR value <0.9. In these patients the OCT images are used by the operators in order to decide whether and how to optimise the result of stenting (see chapter 10.5 – Treatment guidelines for FFR/OCT guided PCI optimisation). If further optimisation was carried out, it is recommended to conclude the intervention by repeated assessment of FFR and intravascular imaging. If no further stent-optimisation was to be performed the coronary intervention is finished. Procedural details including details of the PCI, the FFR measurements and intravascular imaging studies (OCT-studies) at all stages will be recorded for the MD-OPCI study.

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- Arm 2: **a total of 100 people**
  - Data collected during treatment are systematically recorded and subsequently analyzed.

  The study project runs as follows:

  1. Review of inclusion and exclusion criteria

  2. Carrying out the normal cardiac catheterization followed by stent implantation

  3. The result of stent implantation is checked by OCT and FFR (fractional flow rate).
  4. If necessary, optimize the stent based on the previously obtained images
  The optimization of the stent is performed on the basis of clearly defined criteria. Here are basically two scenarios imaginable:
  1) the already implanted stent can be inflated by a balloon to achieve an optimal size of the stent or 2) to optimally treat the diseased coronary vessel it may be necessary to implant additional stents.

  For data-analysis the study population will be divided into two groups according to the post-PCI FFR recording; Group A and B.

  Group B includes all patients with an FFR ≥0.9. As this FFR value can be considered satisfactory, no further optimisation is usually attempted unless the OCT shows major stent related issues and the PCI is finished. Procedural details including details of the PCI, the FFR measurements and intravascular imaging studies (OCT-studies) at all stages will be recorded for the MD-OPCI study.
  Further treatment is stationary.
  In the context of the study, an FU takes place after 12 months by means of a "telephone visit" by a member of the study team on the current condition of the patient

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
-

Study Type: **Non-interventional**

Study Type Non-Interventional: **Observational study**

Allocation: **Non-randomized controlled trial**

- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Other**
- Purpose: **Diagnostic**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

To assess the impact of a study specific treatment algorithm on final FFR after PCI measured in the target vessel:
- baseline versus proportion of patient with FFR measured at the end of optimisation procedure (final FFR)

Secondary Outcome

The MD-OPCI study aims to assess the frequency of intracoronary pathologies after PCI that potentially lead to an impaired FFR using OCT according to CLI-OPCI II study criteria:

1. Frequency of:

-Stent-edge dissection

-Geographical miss/Reference lumen narrowing

-Stent-malapposition

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Universitätsklinik für Kardiologie und Angiologie, Magdeburg**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2018/03/01**
- Target Sample Size: **100**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **30 Years**
- Maximum Age: **90 Years**

Additional Inclusion Criteria

- Participant is willing and able to give informed consent for participation in the study
- Angiogram shows haemodynamically relevant complex lesion (ACC–AHA class B2/C) suitable for PCI and suitable for the use of intravascular imaging (OCT)

Exclusion criteria

The participant may not enter the study if ANY of the following are known to

apply:

-Patients in whom safety or clinical concerns preclude participation.

Addresses

- **Primary Sponsor**

  Universitätsklinik für Kardiologie und Angiologie
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Sources of Monetary or Material Support

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

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Status

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

Trial Publications, Results and other documents

** 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.*