Trial Description

Title

Effects of visualization of successful revascularization on chest pain and quality of life

Trial Acronym

The PLA-pCi-EBO-Trial

URL of the trial

[---]*

Brief Summary in Lay Language

Coronary artery disease is a very common disease in the age group of 40-79 years in Germany. Despite an elevated risk of myocardial infarction and heart failure, chest pain and shortness of breathare symptoms that often lead to reduced quality of life. Treatment of these symptoms is often insufficient. In studies of drugs that help to reduce chest pain and shortness of breath, there was often a large placebo effect. This means that not only the patients that received the actual drug but also the patients that received a pill without the drug reported an amelioration of the discomfort. There are many possible explanations of this so called placebo effect. One involves that patients that take part in a trial are more carefully examined and receive more detailled explanations about their disease. This study is designed to further examine this explanation. Therefore, 134 patients will be randomized by chance into two groups. Patients that have chest pain and a newly implanted stent can participate in this study. All patients will be treated according to the current guidelines and recommendations. One half of the patients will only receive an oral explanation of the procedure and the results and the written report as it is currently the usual clinical practice. The other half wil receive a print out of the pictures of the procedure before and after stent implantation. The symptoms of chest pain and quality of life will be evaluated during the hospital stay as well as one and six months after using a questionnaire.

Brief Summary in Scientific Language

Coronary heart disease is a highly prevalent condition and despite optimal treatment, symptoms including dyspnea and pain from angina pectoris are often only poorly controlled. Past studies showed large placebo effects of medical or interventional treatment.
The objective of this study is to examine the effect of the visual demonstration of the successful coronary intervention on quality of life and pain due to angina pectoris symptoms in patients with relevant coronary stenosis receiving interventional treatment.
After randomization, the intervention group receives a picture of the coronary stenosis before and after successful coronary intervention. The control group will receive a written report.
The Seattle Angina Questionnaire and the NYHA score which will be measured at hospital admission, 1 and 6 months after the coronary intervention in order to determine a potential effect on chest pain with a possible resulting improvement

on quality of life.
This study is designed as a pilot study to allow for a precise estimation for further confirmatory studies.

Organizational Data

- DRKS-ID: **DRKS00017524**
- Date of Registration in DRKS: **2019/07/05**
- 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.: **19-1261-101 , Ethikkommission an der Universität Regensburg**

Secondary IDs

Health condition or Problem studied

- ICD10: **I25 - Chronic ischaemic heart disease**

Interventions/Observational Groups

- Arm 1: **The patients in the intervention group receive a print out of the pictures of the procedure before and after stent implantation.**
- Arm 2: **Control group: According to current clinical praxis, the patient receives a brief explanation and a written report of the angioplasty.**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **investigator/therapist**
- Control: **Other**
- Purpose: **Other**
- Assignment: **Parallel**
- Phase: **N/A**

Study Type: **Interventional**

Study Type Non-Interventional: **[---]***

Allocation: **Randomized controlled trial**

Blinding: **[---]***

Who is blinded: **investigator/therapist**

Control: **Other**

Purpose: **Other**

Assignment: **Parallel**

Phase: **N/A**

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

Primary Outcome

The Seattle Angina Questionnaire (SAQ) derived Quality of life score is assessed during the hospital stay of the angioplasty. This is repeated after 1 and 6 months in a phone interview. Primary endpoint of this study is the change in the quality of life as it is meassured in the Seattle Angina Questionnaire one and six months after stent implantation. This questionnaire is filled out by the study doctor together with the patient during the initiatl hospital stay. The follow up after 1 and 6 months is performed in a telephone interview.

Secondary Outcome

Secondary endpoints are changes in the other derived SAQ-Scores (physical limitation, angina stability, Angina frequency, treatment satisfaction, disease perception) and the dyspnea (NYHA Score) after 1 and 6 months compared to the intial assessment during the initial hospital stay.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Regensburg**
- Medical Center **St. Josef Krankenhaus, Regensburg**
- University Medical Center **Leipzig**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2019/07/07**
- Target Sample Size: **134**
- 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

- symptomatic CAD (coronary artery disease)
- CCS >=2 (Canadian Cardiovascular Society)
- AP-frequency >=2/week
- German-speaking

Exclusion criteria

- EF <35% (ejection fraction)
- severe pulmonary disease
- impaired vision
- impaired hearing
- dementia
- drugs with influence on the opiod system
- high grade valve impairment
- Hb <=7 mg/dL
- participation in other interventional clinical trial

Addresses

- **Primary Sponsor**

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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 planned**
- Study Closing (LPLV): **[---]***

Trial Publications, Results and other documents

- Approval of ethics comm. (mandatory for transfer to Studybox) **Votum Ethikkommission**

** 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.*