Trial Description

Title

Selective depletion of C-reactive protein by therapeutic apheresis (CRP-apheresis) in acute myocardial infarction

Trial Acronym

[---]*

URL of the trial

[---]*

Brief Summary in Lay Language

CAMI1 is a clinical trial to investigate the reduction of C-reactive protein (CRP) by therapeutic apheresis (CRP-apheresis) in patients after acute myocardial infarction. Mandatory requirement is stenting as primary treatment.
The term therapeutic apheresis commonly refers to medical procedures, where pathogenic constituents are removed from the circulating blood. Elimination is performed by adsorbers in an extracorporeal circulation. For removal of the pathogenic substances, the plasma is separated from the blood (circulation) to pass the adsorber. The purified plasma is merged with the solid blood components thereafter and returned to the patient.
The adsorber "PentraSorb® CRP" used for CRP apheresis is CE-certified. It is designated to the selective depletion of C-reactive protein from human blood plasma.
The CAMI1-trial aims to investigate the reduction of tissue damage (including reperfusion damage) after acute myocardial infarction by CRP apheresis, and if secondary complications (e.g. the emergence of heart failure) can thus be counteracted.
It is believed that CRP, as an inflammatory mediator, promotes the destruction of the heart muscle tissue (in interaction with complement) and affects the regeneration of the ischemic tissue adversely.
A possible protective effect of CRP-apheresis with respect to the development of secondary complications is supposed to be determined by means of cardiac magnetic resonance imaging (CMRI) by the functional parameters "size of the infarcted area" and "left ventricular ejection fraction".

Amendment of Feb. 24, 2017:
Both intervention groups were pooled and for all patients the start of treatment was expanded to 10 - 36 hours and the treatment intervals to 24 ± 12 hours. Furthermore the period for the performance of the first MRI of the heart was expanded to 5 ± 3 days.

Brief Summary in Scientific Language

CAMI1 is an open-label, controlled multicentre trial.
It examines the efficacy and tolerability of CRP apheresis in patients after primary treatment of acute myocardial infarction. Two treatment groups differ in terms of start of the CRP apheresis after the infarction and in the intervals of treatments.

Comparison of the results (verum / controls) is carried out by matched-pairs analyses.

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

[---]*

Description IPD sharing plan

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Organizational Data

- DRKS-ID: **DRKS00008988**
- Date of Registration in DRKS: **2015/08/06**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **no**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **042/15 (I) , Ethikkommission der Ärztekammer Schleswig-Holstein (Ethik-Kommission I)**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1172-6428**
- EUDAMED-No.
  (for studies acc. to Medical Devices act): **CIV-15-06-013630**

Health condition or Problem studied

- ICD10: **I21 - Acute myocardial infarction**

Interventions/Observational Groups

- Arm 1: **40 patients will receive 2 treatments with an interval of 24 ± 12 hours (after start of the previous treatment). The first treatment starts 10 - 36 hours after the onset of symptoms of myocardial infarction. If approximately 6 hours after the end of the second treatment the CRP-concentration rises to values above 30 mg/l, a third treatment will be performed.**
  In each treatment up to 6000 ml of plasma are being processed, preferred in 6 cycles of 1000 ml (change of loading and regeneration of the adsorber). The duration of one treatment is approx. 4 - 6 hours.

- Arm 2: **In addition to the standard treatment of acute myocardial infarction, the 40 patients of the control group receive two MRI scans of the heart 5 ± 3 days**

resp. 12 ± 2 weeks after the infarction. In addition, the CRP levels are determined in these patients for four days at intervals of 12 hours from the onset of symptoms.

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Non-randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Control group receives no treatment**
- Purpose: **Treatment**
- Assignment: **Other**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Size of the infarcted area, determined by MRI, 5 ± 3 days as well as 12 ± 2 weeks after myocardial infarction.

Secondary Outcome

• Incidence of expected and unexpected adverse effects of the CRP-apheresis
• LVEF (left ventricular ejection fraction), determined by MRI of the heart 5 ± 3 days as well as 12 ± 2 weeks after the infarction.
• Major adverse cardiac events (MACE) 6 and 12 months after the infarction.
MACEs are defined as follows: death from any cause, non-fatal re-infarction or stroke, unstable angina pectoris, congestive heart failure leading to inpatient treatment and coronary revascularization (percutaneous coronary angioplasty or coronary artery bypass). The time until occurance of the first event is regarded as end point.

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Medizinische Klinik – Innere Medizin, Diakonissenkrankenhaus Flensburg , 24939 Flensburg**

- Medical Center **Herz- und Gefäßzentrum Oberallgäu-Kempten, 87439 Kempten/Allgäu**
- Medical Center **Klinik für Innere Medizin - Kardiologie, Angiologie, Nephrologie und konservative Intensivmedizin, Vivantes Klinikum Neukölln, 12351 Berlin**
- University Medical Center **Medizinische Klinik / Kardiologie, Medizinische Fakultät "Carl Gustav Carus“, Technische Universität Dresden, 01309 Dresden**
- University Medical Center **ECOS Studienzentrum / Universitätsmedizin Rostock, 18057 Rostock**
- Medical Center **Herz- und Gefäßzentrum Oberallgäu-Kempten, 87509 Immenstadt**
- University Medical Center **Zentrum Innere Medizin (ZIM), 97080 Würzburg**
- Medical Center **Kardiologie am Immanuel Klinikum Bernau, Herzzentrum Brandenburg, 16321 Bernau bei Berlin**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2015/11/02**
- Target Sample Size: **80**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **80 Years**

Additional Inclusion Criteria

• STEMI as defined by the guidelines of the European Society of Cardiology (ESC) for the treatment of AMI in patients with ST-segment elevation.
• TIMI III flow after PCI (stent implantation)
• Killip-Class ≤ II
• 2 - 12 h from onset of symptoms until coronary reperfusion
• Informed consent
• Legal competence

Exclusion criteria

• Previous myocardial infarction
• Acute infectious disease (body temperature (auricular, sublingual) > 38.0 °C)
• Systolic blood pressure < 100 mmHg
• Known hypersensitivity to therapeutic apheresis
• Cardiogenic shock
• Dialysis dependent renal insufficiency
• Previous coronary artery bypass surgery

- **Contraindication for MRI (e.g. non-MRI-capable implants, claustrophobia)**
- **Malignant or chronic inflammatory disease**
- **Pregnancy or lactation period**
- **Limited possibility to join the follow-up examination (e.g., patient lives abroad)**
- **Participation in other interventional trials**

Addresses

■ **Primary Sponsor**

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Sources of Monetary or Material Support

- **Commercial (pharmaceutical industry, medical engineering industry, etc.)**

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Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2019/11/22**

Trial Publications, Results and other documents

- Paper **Ries, W., Torzewski, J., Heigl, F. et al. C-Reactive Protein Apheresis as Anti-inflammatory Therapy in Acute Myocardial Infarction: Results of the CAMI-1 Study. Frontiers in Cardiovascular Medicine. 2021;8(155)**

** 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.*