Trial Description

Title

Registry for CRP apheresis after acute myocardial infarction

Trial Acronym

CAMI-Registry

URL of the trial

http:///

Brief Summary in Lay Language

The prognostic value of C-reactive protein (CRP) in assessing the course of acute myocardial infarction (AMI) is well known: The higher the increase in CRP in the days following the infarction, the worse the prognosis.
With CRP apheresis, the increase in CRP can be effectively limited, which can lead to an improved prognosis. CRP apheresis is a therapeutic haemapheresis procedure in which the C-reactive protein is selectively and effectively removed from the patient's plasma in an extracorporeal circuit using a regenerable adsorber. To remove the pathogenic substance, plasma is separated from a continuous blood circuit and passed through an adsorber. The purified plasma is then recombined with the solid blood components and returned to the patient. The frequency and intervals of the treatments depend on the initial CRP concentration. In addition to the immediate effects, particular interest lies in the assessment of the course of the disease in the first 30 days and 12 months after the infarction.
The CAMI registry is intended to map the course of the disease and the examination/treatment, especially of AMI patients following guideline-based primary therapy, for whom elevated CRP values were measured (target population).
The pseudonymised data will be used to extend the experience on the clinical efficiency of CRP apheresis, to optimise the quality of the therapeutic application and to identify possible treatment or device-associated complications as early as possible.
All relevant information such as diagnosis, concomitant diseases, therapeutic measures, medication, disease status and clinical laboratory parameters on the course of treatment are documented in the registry.
The data collected are regularly evaluated and published.
The CAMI registry is an effective tool to create the data basis for justifying and optimising medical decisions. The heterogeneity of the patient group also makes it possible to identify subgroups whose risk-benefit profile can be evaluated in a differentiated manner.

Brief Summary in Scientific Language

The CAMI registry is carried out multicentrally as a non-interventional study (NIS). It offers the possibility to systematically record a new treatment option, the CRP apheresis, for the targeted reduction of CRP level after guideline-based primary treatment of acute myocardial infarction. In CRP apheresis, CRP is selectively

removed from the plasma in an extracorporeal circuit using an adsorber. The number of treatments depends on the level of the CRP concentration. Usually 2-3 treatments are carried out, each of which processing 1.5 - 2.5 times the plasma volume.

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

[---]*

Description IPD sharing plan

[---]*

Organizational Data

- DRKS-ID: **DRKS00017481**
- Date of Registration in DRKS: **2019/06/28**
- 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.: **19004 , Ethik-Kommission der Bayerischen Landesärztekammer**

Secondary IDs

- Universal Trial Number (UTN): **U1111-1234-9723**

Health condition or Problem studied

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

Interventions/Observational Groups

- Arm 1: **Patients with elevated CRP levels following guideline-based primary treatment of acute myocardial infarction may be treated with the CRP apheresis as a new treatment option for the targeted reduction of the CRP concentration.**
  The CAMI registry is intended to document the course of the disease and the examination/treatment of these patients in particular. All relevant information such as diagnosis, concomitant diseases, therapeutic measures, medication, disease status as well as clinical laboratory parameters over the course of treatment will be recorded. In addition, the evaluation of the course of the disease in the first 30 days and 12 months after the infarct is of particular interest.

Characteristics

- 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): **N/A**

Primary Outcome

Occurrence of cardiac events 30 days and 12 months after acute myocardial infarction

Secondary Outcome

**Heart pumping capacity (left ventricular ejection fraction, LVEF),
Myocardial tissue damage in neuroimaging procedures,
occurrence of undesirable effects of CRP apheresis.**

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Herz- und Gefäßzentrum Oberallgäu-Kempten, 87439 Kempten/Allgäu**
- Medical Center **Diakonissenkrankenhaus Flensburg, Medizinische Klinik – Innere Medizin, 24939 Flensburg**
- University Medical Center **Medizinische Klinik / Kardiologie, Medizinische Fakultät "Carl Gustav Carus“, Technische Universität Dresden, 01309 Dresden**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2019/06/25**

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- Target Sample Size: **300**
- 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

Acute myocardial infarction after guideline primary treatment, elevated CRP concentration, CRP-apheresis

Exclusion criteria

None

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 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.*