Trial Description

Title

CRP apheresis registry for COVID-19

Trial Acronym

CACOV-registry

URL of the trial

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Brief Summary in Lay Language

The CACOV registry is a non-interventional study (observational study) to investigate the reduction of C-reactive protein (CRP) by therapeutic apheresis (CRP apheresis) in patients with COVID-19.
The term therapeutic apheresis generally refers to medical procedures whose therapeutic effect is based on the elimination of components of the blood to which a pathogenic function is attributed in the context of disease processes. The elimination takes place in adsorbers outside the body in an extracorporeal circuit. To remove the pathogenic substances, plasma is separated from the blood (circulation) and passed through the adsorber. The purified plasma is then recombined with the solid blood components and returned to the patient.
The "PentraSorb® CRP" adsorber used for CRP apheresis is CE-certified for the selective removal of C-reactive protein from human plasma.

Brief Summary in Scientific Language

The CACOV registry is being conducted on a multicenter basis.
It offers the possibility to systematically record CRP apheresis, a new treatment option for the targeted reduction of CRP levels in COVID-19. Apheresis treatments will be performed in parallel to therapy according to S2k guideline - recommendations for inpatient therapy of patients with COVID-19 of DGIIN, DIVI and DGP.
In CRP apheresis, CRP is selectively removed from plasma in an extracorporeal circuit using an adsorber. The frequency and intervals of the treatments depend on the initial CRP concentration. In general, 1.5 - 2.5 times the plasma volume is processed at a time.

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

No

Description IPD sharing plan

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Organizational Data

- DRKS-ID: **DRKS00024376**
- Date of Registration in DRKS: **2021/05/04**
- 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.: **Eth-28/21 , Ethik-Kommission der Ärztekammer Berlin**

Secondary IDs

Health condition or Problem studied

- Free text: **U07.1 COVID-19**

Interventions/Observational Groups

- Arm 1: **CRP apheresis according to the instructions for use of the adsorber PentraSorb CRP in patients with COVID-19**

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

CRP progression

Secondary Outcome

Length of stay in hospital
- Length of stay in the intensive care unit
- Days of mandatory ventilation
- mortality
- Pulmonary tissue damage
- Myocardial tissue damage
- Inflammation markers
- Incidence of adverse effects of CRP apheresis

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- Medical Center **Gemeinschaftskrankenhaus Havelhöhe, 14089 Berlin**
- Medical Center **Herz- und Gefäßzentrum Oberallgäu-Kempten, 87439 Kempten/Allgäu**
- Medical Center **Marienhospital Gelsenkirchen, 45886 Gelsenkirchen**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2021/05/14**
- Target Sample Size: **1000**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **no minimum age**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

COVID-19, CRP-apheresis

Exclusion criteria

none

Addresses

■ **Primary Sponsor**

Pentracor GmbH
Neuendorfstr. 23 b/d
16761 Hennigsdorf
Germany

Telephone: **[---]***
Fax: **[---]***
E-mail: **info at pentracor.de**
URL: **www.pentracor.de**

■ **Contact for Scientific Queries**

Pentracor GmbH
Mr. Dr. Burghard Thiesen
Neuendorfstr. 23 b/d
16761 Hennigsdorf
Germany

Telephone: **+49 (0)3302 209449-35**
Fax: **+49 (0)3302 20944999**
E-mail: **thiesen at pentracor.de**
URL: **www.pentracor.de**

■ **Contact for Public Queries**

Pentracor GmbH
Mr. Dr. Burghard Thiesen
Neuendorfstr. 23 b/d
16761 Hennigsdorf
Germany

Telephone: **+49 (0)3302 209449-35**
Fax: **+49 (0)3302 20944999**
E-mail: **thiesen at pentracor.de**
URL: **www.pentracor.de**

Sources of Monetary or Material Support

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

Pentracor GmbH
Neuendorfstr. 23 b/d
16761 Hennigsdorf
Germany

Telephone: **+49 (0)3302 209 449 0**
Fax: **+49 (0)3302 209 449 99**
E-mail: **info at pentracor.de**
URL: **www.pentracor.de**

Status

- Recruitment Status: **Recruiting ongoing**
- Reason, if "Recruitment stopped after recruiting started" or "Recruiting withdrawn before recruting started": **[---]***
- Reason, if Reason for Recruiting Stop "Other": **[---]***
- Study Closing (LPLV): **[---]***
- Number of Participants in Germany after Recruiting complete: **[---]***
- Total Number of Participants (all Sites worldwide) after Recruiting complete: **[---]***

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.*