Trial Description

Title

Cytokine adsorption in severe COVID-19 pneumonia requiring extracorporeal membrane oxygenation

Trial Acronym

CYCOV

URL of the trial

[---]*

Brief Summary in Lay Language

The primary goal is to investigate the efficacy of treatment with a CytoSorb® cytokine adsorber in patients with severe COVID-19 disease requiring venous ECMO over 72 hours after initiation of ECMO.

Brief Summary in Scientific Language

The primary goal is to investigate the efficacy of treatment with a CytoSorb® adsorber in patients with severe COVID-19 disease who require venous ECMO over 72 hours after initiation of ECMO. The primary endpoint is the reduction of interleukin-6 72 hours after initiation of ECMO support. Secondary endpoints include 30-day survival, vasopressor and volume requirements, and lactate.

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

No

Description IPD sharing plan

the study protocol and the statistical analysis plan will be published with the publication of the study results

Organizational Data

- DRKS-ID: **DRKS00021300**
- Date of Registration in DRKS: **2020/04/08**
- Date of Registration in Partner Registry or other Primary Registry: **2020/03/27**
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **168/20 , Ethik-Kommission der Albert-Ludwigs-Universität Freiburg**

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Secondary IDs

- Primary Registry-ID: **NCT04324528 (clinicaltrials.gov)**
- Other Secondary-ID: **DRKS00021248 (Hauptstudie)**

Health condition or Problem studied

- Free text: **SARS-CoV-2-infection (COVID-19-disease) with severe pneumonia**
- ICD10: **U07.1 - Emergency use of U07.1**

Interventions/Observational Groups

- Arm 1: **V-V ECMO with cytokine adsorption using a CytoSorb adsorbers for 72 hours**
- Arm 2: **V-V ECMO without cytokine adsorption**

Characteristics

- Study Type: **Interventional**
- Study Type Non-Interventional: **[---]***
- Allocation: **Randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Active control (effective treament of control group)**
- Purpose: **Treatment**
- Assignment: **Parallel**
- Phase: **II-III**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

IL-6 at 72 hours after initiation of V-V ECMO

Secondary Outcome

30d survival, ICU survival, katecholamine dosage, urine output, fluid demand, lactate

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Freiburg im Breisgau**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2020/03/29**
- Target Sample Size: **30**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **100 Years**

Additional Inclusion Criteria

SARS-CoV-2-infection, vv-ECMO

Exclusion criteria

pregnancy

Addresses

■ **Primary Sponsor**

Universitätsklinikum Freiburg
Mr. Dr., MPH Alexander Supady
Hugstetter Strasse 55
79106 Freiburg
Germany

Telephone: **0761/270-73790**
Fax: **[---]***
E-mail: **alexander.supady at universitaets-herzzentrum.de**
URL: **www.uniklinik-freiburg.de**

■ **Contact for Scientific Queries**

Universitätsklinikum Freiburg
Mr. Dr., MPH Alexander Supady
Hugstetter Str. 55
79106 Freiburg
Germany

Telephone: **0761/270-73790**
Fax: **[---]***
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Mr. Dr., MPH Alexander Supady
Hugstetter Str. 55
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Fax: **[---]***
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Sources of Monetary or Material Support

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

Universitätsklinikum Freiburg
Hugstetter Strasse 55
79106 Freiburg
Germany

Telephone: **[---]***

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Status

- Recruitment Status: **Recruiting complete, follow-up complete**
- Study Closing (LPLV): **2021/01/27**

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.*