

**PLEASE NOTE:** *This trial has been registered retrospectively.*

## Trial Description

### Title

**SARS-CoViD-Endotheliitis Study via Retinal Vascular Analysis (COVID-19)**

### Trial Acronym

**VoViThel**

### URL of the trial

[---]\*

### Brief Summary in Lay Language

**The novel Coronavirus Triggers a disease (CoViD-19) that affects millions of People worldwide. Up until now knowledge is scarce. Especially prognosticytion is difficult. Coronavirus does affect the vascular architecture. In our study we investigate the blood vessels in the eye. We want to show that alterations in dynamic and static Parameters in the vessel can be used to better prognosticate the course of the CoVi-19 disease.**

### Brief Summary in Scientific Language

**We measure the width of ertinal aretiolles and venoles as well as the dynmaic changes of These Parameters after Stimulation by flicker-light. We test the association for These parameters with the probability of an intensive care therapy.**

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

**No**

### Description IPD sharing plan

**informed consent at the Moment does not include data-sharing.**

## Organizational Data

- DRKS-ID: **DRKS00023334**
- Date of Registration in DRKS: **2020/10/30**
- Date of Registration in Partner Registry or other Primary Registry: [---]\*
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**

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Investigator Sponsored/Initiated Trial (IST/IIT): **yes**

- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **2020-1805BO , Ethikkommission der Friedrich-Schiller-Universität Jena an der Medizinischen Fakultät**

## Secondary IDs

## Health condition or Problem studied

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

## Interventions/Observational Groups

- Arm 1: **Patients with CoViD-19 are teste via dynamic and static retinal vessel analysis, if hospitalisation is ongoing we measure them weekly. After discharge there is a final measurement 6 weeks after discharge together with the post CoViD-19 visit.**

## Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Single arm study**
- Blinding: [---]\*
- Who is blinded: [---]\*
- Control: **Uncontrolled/Single arm**
- Purpose: **Diagnostic**
- Assignment: **Single (group)**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

## Primary Outcome

## **Association of FID art, FID ven, FIC art (Parameters of dynamic vessel Analysis) with the parameter "Intensive Care Therapy"**

### **Secondary Outcome**

**FID art, FID ven and FIC art differ significantly during CoViD-19 in comparison to normal values**

**CRAE, CRVE, CRAE/CRVE Ratio (Parameters of static vessel Analysis) differ significantly during CoViD-19 in comparison to normal values**

**FID art, FID ven and FIC art Change during the course of CoViD-19**

**Association of the aforementioned Parameters with Ventilation**

**The predictive value of FID art, FID ven, FIC art are better than CrP**

### **Countries of recruitment**

- **DE Germany**

### **Locations of Recruitment**

- **University Medical Center Jena**

### **Recruitment**

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2020/09/14**
- 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: **no maximum age**

### **Additional Inclusion Criteria**

**CoViD-19**

### **Exclusion criteria**

**photosensitive epilepsie, elevated intraocular pressure, pregnancy**

## Addresses

### ■ Primary Sponsor

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### ■ Contact for Public Queries

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## Sources of Monetary or Material Support

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

**Klinik für Kinder- und Jugendmedizin  
Am Klinikum 1  
07747 Jena**

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Telephone: [---]\*

Fax: [---]\*

E-mail: [---]\*

URL: [---]\*

## 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.