Trial Description

Title

Long-term consequences of COVID-19 for pulmonary and neurocognitive disorders

Trial Acronym

COVIMMUNE-Clin

URL of the trial

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Brief Summary in Lay Language

This study investigates potential longterm effects of a SARS-CoV-2-infection on the nervous system and memory performance as well as pulmonological functions and lung tissue.

Brief Summary in Scientific Language

This study is a prospective comparison of neurocognitive function and pulmonological sequelae following SARS-CoV-2 infection. Subjects with asymptomatic disease progression, severe disease progression and subjects from a control group are compared at three measurement points over a period of 12 months.

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

No

Description IPD sharing plan

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Organizational Data

- DRKS-ID: **DRKS00023806**
- Date of Registration in DRKS: **2021/03/16**
- Date of Registration in Partner Registry or other Primary Registry: **[---]***
- Investigator Sponsored/Initiated Trial (IST/IIT): **yes**
- Ethics Approval/Approval of the Ethics Committee: **Approved**
- (leading) Ethics Committee Nr.: **511/20 , Ethik-Kommission der Medizinischen Fakultät der Rheinischen Friedrich-Wilhelms-Universität Bonn**

Secondary IDs

Health condition or Problem studied

- ICD10: **U07.1 - Emergency use of U07.1**
- Free text: **SARS-CoV-2**

Interventions/Observational Groups

- Arm 1: **Recovered patients after asymptomatic course of SARS-CoV-2 infection. Patients undergo cognitive, neurological (including MRI) and pneumonological examinations.**
- Arm 2: **Recovered patients after severe SARS-CoV-2 positive. Subjects undergo cognitive, neurological (including MRI) and pneumonological examinations.**
- Arm 3: **Healthy controls. Subjects undergo cognitive, neurological (including MRI) and pneumonological examinations.**

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Other**
- Allocation: **Non-randomized controlled trial**
- Blinding: **[---]***
- Who is blinded: **[---]***
- Control: **Other**
- Purpose: **Other**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Primary endpoint of the investigation ist the total episodic memory score taken from the long delayed verbal recall parameters of the Auditive Word List Test (AWLT) from within the Vienna Test System Cognitive Functions Dementia (Kognitive Funktionen Demenz) Version 2 - Revision 2 von Mödling, Jänner 2019 at the 12 month visit.

Secondary Outcome

Secondary endpoints are as follows:
- Neurodegeneration assessed by volumetric MRI
- Changes in serum biomarkers of neurodegeneration
- Pulmonary dysfunction and development of lung fibrosis
- Activities of daily living
- Health-related quality of life

Countries of recruitment

- DE **Germany**

Locations of Recruitment

- University Medical Center **Bonn**

Recruitment

- Planned/Actual: **Planned**
- (Anticipated or Actual) Date of First Enrollment: **2021/04/08**
- Target Sample Size: **150**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **25 Years**
- Maximum Age: **75 Years**

Additional Inclusion Criteria

Patient subjects must belong to one of the following: Asymptomatic or severly affected course of COVID-19 (SARS-CoV-2 positive) infection. Both groups must meet the following criteria:
- written informed consent of the subject
- aged 25 to 75 years
- fulfill the criteria for the respective groups of interest; either to the group of remitted COVID-19 infection cases with an asymptomatic couse (i.e., no symptoms other than anosmia and/or ageusia) or to the group of remitted COVID-19 infection cases with a severe course (i.e., requiring hospital stay)
- able and willing to participate throughout the study
- fluent German language abilities

Healthy controls will only be included if they meet all of the following criteria

- written informed consent
aged 25 to 75 years
fluent German language abilities
- deny memory concerns
- memory performance is above - 1.0 SD od the mean on a cognitive screening of episodiv memory impariment
- no substance abuse
- no known history of or current diagnosed psychiatric illness

Exclusion criteria

- inability to give informed consent
- any condition that clearly interferes with participation in the study
- any condition that interferes with the clinical or neuropsychological study procedures
- sensory impairment that prevents or significantly interferes with neuropsychological testing
- contraindication for MRI
- severe or unstable medical condition
- current major depressive episode
- psychotic disorder, bipolar disorder, substance abuse at present or in the past
- known neurodegenerative disorder (Alzheimer's disease, Parkinson's disease, Frontotemporal dementia, Huntington's disease, Amyotrophic Lateral Sclerosis)
- vascular dementia, history of stroke, or history of malignant disease

Addresses

■ **Primary Sponsor**

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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.*