Trial Description

Title

Prospective validation of a proteomic urine test for early and accurate prognosis of critical course complications in patients with SARS-CoV-2 infection

Trial Acronym

Crit-Cov-U

URL of the trial

[---]*

Brief Summary in Lay Language

The investigation of protein fragment patterns in urine (urine proteomics) is intended to predict the severity of Covid-19 disease.

Brief Summary in Scientific Language

Three urine samples are collected from each patient or sent from home, a first urine sample at the time of the first presentation (day 0-1), a second on day 4-5 and a third on day 10-14, to determine the best time to collect the sample for prognostic purposes. A classification into moderate, severe and critical courses of disease is carried out according to the WHO classification criteria (to be found at: https://www.who.int/docs/default-source/coronaviruse/who-china-joint-mission-on-covid-19-final-report.pdf), which also includes intensive care, ventilation and death as patient-relevant endpoints.
The urine samples are collected, prepared, measured by CE-MS, evaluated and patient-specific peptide lists prepared according to established SOP specifications and in conformity with ISO standard 13485/2016. The peptide profiles of the first 250 patients at all sample times will be used to verify the 31 peptide markers associated with the severity of SARS-CoV-2 infection identified in the pilot study. The higher statistical power will also be used to search for additional peptide markers that show a correlation to the severity of SARS-CoV-2 infection. Based on the results of the statistical analysis, the COVID31 classification model established in a previous pilot study will be adapted. By classifying the first 250 patients at all sample times, the threshold value for a positive test result is determined with regard to the prediction of a critical course of disease in total cross-validation. The completion of the first phase of model optimization is documented before the model is then validated prospectively in routine operation on a further 750 patients using the predetermined threshold value for a positive test result. The final evaluation of the study will be performed using the established statistical methods Receiver Operating Characteristics and Precision Recall curves, as well as univariate and multivariate Cox regression analyses.

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

No

Description IPD sharing plan

N.a.

Organizational Data

- DRKS-ID: **DRKS00022495**
- Date of Registration in DRKS: **2020/08/25**
- 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.: **EK-BR-88/20-1 , Ethikkommission bei der Sächsischen Landesärztekammer**

Secondary IDs

Health condition or Problem studied

- ICD10: **U07.1 - Emergency use of U07.1**

Interventions/Observational Groups

- Arm 1: **Not applicable (observational study)**
  Patients are screened for their urinary proteome and compared whether a proteome risk score is associated with the clinical severity of Covid-19 disease

Characteristics

- Study Type: **Non-interventional**
- Study Type Non-Interventional: **Observational study**
- Allocation: **Other**
- Blinding: **[---]***
- Who is blinded: **patient/subject, investigator/therapist, caregiver**
- Control: **Other**
- Purpose: **Prognosis**
- Assignment: **Factorial**
- Phase: **N/A**
-

Study Type: **Non-interventional**

Study Type Non-Interventional: **Observational study**

Allocation: **Other**

Blinding: **[---]***

Who is blinded: **patient/subject, investigator/therapist, caregiver**

Control: **Other**

Purpose: **Prognosis**

Assignment: **Factorial**

Phase: **N/A**

Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

Primary Outcome

Predictive strength of a urine protein fragment pattern (proteomics) for the severity of Covid19 disease

Secondary Outcome

Best time-point to use the urinary proteomic test for severity prediction of Covid-19 disease

Countries of recruitment

- DE **Germany**
- AT **Austria**

Locations of Recruitment

- Medical Center **Leipzig**

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2020/08/01**
- Target Sample Size: **1000**
- Monocenter/Multicenter trial: **Multicenter trial**
- National/International: **International**

Inclusion Criteria

- Gender: **Both, male and female**
- Minimum Age: **18 Years**
- Maximum Age: **no maximum age**

Additional Inclusion Criteria

Covid-19 disease
Ability for informed consent

Exclusion criteria

Anuria

Addresses

- **Primary Sponsor**

  Medizinische Hochschule Hannover HannoverClinical Trial Center
  Mr. Prof. Dr. med. Heiko von der Leyen
  Carl-Neuberg-Str. 1
  30625 Hannover
  Germany

  Telephone: **+49 511 532 115-10**
  Fax: **[---]***
  E-mail: **vonderLeyen.Heiko at mh-hannover.de**
  URL: **www.mh-hannover.de**
- **Contact for Scientific Queries**

  Klinik für Infektiologie, Nephrologie, Rheumatologie
  Mr. Prof. Dr. med. Joachim Beige
  Delitzscher Strasse 141 / Haus 54
  04129 Leipzig
  Germany

  Telephone: **0341/9092613**
  Fax: **[---]***
  E-mail: **Joachim.Beige at kfh-dialyse.de**
  URL: **www.sanktgeorg.de/nephro.html**
- **Contact for Public Queries**

  Medizinische Hochschule HannoverHannover Clinical Trial Center
  Mr. Prof. Dr. Heiko von der Leyen
  Carl-Neuberg-Str. 1

Contact for Public Queries

Medizinische Hochschule HannoverHannover Clinical Trial Center
Mr. Prof. Dr. Heiko von der Leyen
Carl-Neuberg-Str. 1
30625 Hannover
Germany

Telephone: **+49 (0) 511 532 115-10**
Fax: **[---]***
E-mail: **vonderLeyen.Heiko at mh-hannover.de**
URL: **www.mh-hannover.de**

Sources of Monetary or Material Support

- **Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)**

Bundesministerium für Gesundheit
Rochusstraße 1
53123 Bonn
Germany

Telephone: **030 18441-0**
Fax: **[---]***
E-mail: **poststelle at bmg.bund.de**
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.*