Trial Description

Title
Covid-19 Case-Cluster-Study

Trial Acronym
[---]*

URL of the trial
[---]*

Brief Summary in Lay Language
Epidemiological exposure data and biological samples will be systematically collected and analysed using a standardised protocol (as proposed by the World Health Organisation (WHO)) to provide estimates of the severity of infection and transmission rate/modalities of the COVID 19 virus.

Brief Summary in Scientific Language
The aim of the "Covid-19 Case Cluster Study" is to investigate the prevalence of SARS/CoV-2-positive individuals (degree of infestation) in the population of a high-risk area, the virulence of infection with SARS/CoV-2 and the personal and environmental factors that correlate with the virulence of the virus. For this purpose, a representative sample of a region of the high-risk area of the Heinsberg district will be examined for SARS/CoV-2 infection and correlated with a series of anamnestic data. In addition, environmental diagnostics will be carried out on selected individuals to analyse the transmission pathways of the infection. In a substudy with additional participants of the “Kappensitzung”, an extended questionnaire will be used to examine infection chains and to determine the behaviour and characteristics of the persons that are decisive for infection.

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

Description IPD sharing plan
On request to the sponsor.

Organizational Data

- DRKS-ID: DRKS00021306
- Date of Registration in DRKS: 2020/04/14
DRKS-ID: **DRKS00021306**
Date of Registration in DRKS: **2020/04/14**

- 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.: **Lfd. Nr. 085/20 , Ethik-Kommission der Medizinischen Fakultät der Rheinischen Friedrich-Wilhelms-Universität Bonn**

### Secondary IDs

**Free text:** COVID-19

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

### Health condition or Problem studied

- **Free text:** COVID-19
- **ICD10:** U07.1 - Emergency use of U07.1

### Interventions/Observational Groups

- **Arm 1:** Index persons of the Gangelt register as well as household or family members: Collection of biological samples for virus diagnostics from the study participants:
  - adults: 3 EDTA tubes (10 ml), throat swab, spit (saliva)
  - Children: 1 EDTA tube (1 ml), throat swab, spit (saliva), handing out a study questionnaire
  
  In up to 50 selected households, further virological diagnostics, including the living environment, are to be used to evaluate the extent to which the virus can be transmitted to family members via air and the inanimate environment (surfaces, consumer goods, food, wastewater) and the living environment (pets)

- **Arm 2:** Substudy: Participants of the "Kappenmeeting" residing in the Heinsberg district as well as household or family members: virus diagnostics like observation group 1 and extended questionnaire

### Characteristics

- **Study Type:** Non-interventional
- **Study Type Non-Interventional:** Other
- **Allocation:** Other
- **Blinding:** [--]*
- **Who is blinded:** [--]*
Study Type: **Non-interventional**

Study Type Non-Interventional: **Other**

Allocation: **Other**

Blinding: [---]*

Who is blinded: [---]*

- Control: **Other**
- Purpose: **Prevention**
- Assignment: **Parallel**
- Phase: **N/A**
- Off-label use (Zulassungsüberschreitende Anwendung eines Arzneimittels): **N/A**

### Primary Outcome

The primary endpoint is the prevalence of SARS-CoV-2 positive individuals in the study population, defined as the number of individuals with positive laboratory findings (from at least one of the sample media collected in the study) divided by the total number of study participants.

### Secondary Outcome

Secondary endpoints are

(i) the "level of infestation", defined as the sum of
a. prevalent persons, and
b. healthy individuals with previous positive laboratory findings (prior to the conduct of the study) with concurrent negative laboratory findings in the study, divided by the total number of study participants,

(ii) the rate of unreported cases, defined as the number of persons with positive laboratory results (in the study) but without previous positive laboratory results (before the study was conducted), divided by the total number of study participants,

(iii) the proportion of healthy individuals, defined as the number of individuals with previous positive laboratory results (before the study was conducted) with concurrent negative laboratory results in the study, divided by the total number of study participants,

(iv) the associations of the above measures with the symptoms reported in the questionnaire,

(v) the associations of the above measures with the personal factors recorded in the questionnaire,

(vi) the associations of the above measures with the personal and behavioural factors recorded in the expanded questionnaire; and

(vii) the associations of the above measures with the additional environmental factors collected in the selected households

### Countries of recruitment
DE Germany

Locations of Recruitment

- other Heinsberg

Recruitment

- Planned/Actual: **Actual**
- (Anticipated or Actual) Date of First Enrollment: **2020/03/31**
- Target Sample Size: **1400**
- Monocenter/Multicenter trial: **Monocenter trial**
- National/International: **National**

Inclusion Criteria

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

Additional Inclusion Criteria

- Residence in the Heinsberg district
- Individual surname and random selection as index person (by sampling from the Gangelt municipal register)
- For the substudy: participation in the “Kappensitzung”
- Household or family members of the index person/participants of the "Kappensitzung"

Exclusion criteria

None.

Addresses

- **Primary Sponsor**
  Institut für Virologie/ Universität klinikum Bonn
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Sources of Monetary or Material Support

- Institutional budget, no external funding (budget of sponsor/PI)
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- Public funding institutions financed by tax money/Government funding body (German Research Foundation (DFG), Federal Ministry of Education and Research (BMBF), etc.)
  Ministerium für Arbeit, Gesundheit und Soziales NRW
  Fürstenwall 25
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  Telephone: 02118555
  Fax: [--]*
  E-mail: [--]*
  URL: [--]*

Status

- Recruitment Status: Recruiting complete, follow-up complete
- Study Closing (LPLV): 2020/04/09

Trial Publications, Results and other documents
DRKS-ID: **DRKS00021306**
Date of Registration in DRKS: **2020/04/14**
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* 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.