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Prevalence and associated risk factors of COVID-19 infection experienced by refugees seeking asylum in Berlin

Submission date
17/03/2021

Recruitment status
No longer recruiting

Registration date
19/03/2021

Overall study status
Completed

Last Edited
29/06/2023

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
To date, little research has been conducted regarding the impact of the current global pandemic caused by SARS-CoV-2 on vulnerable populations. Refugees are especially susceptible to medical, psychological and sociological risks. Factors that contribute to these risks include precarious travelling conditions; lack of medical and hygienic care during flight; pre-existing health conditions; chronic stress, malnourishment and fatigue; as well as inadequate or overcrowded housing experienced during their transit. As a consequence, infectious diseases including tuberculosis and cholera have a high chance of manifesting themselves.
According to early reports from Spring 2020, migrants living in refugee camps and shelters were not affected as strongly by COVID-19 infections as other populations living in more stable conditions. It was argued that the geographical and social isolation of these shelters decreased transmission of the virus. However, more recent reports and medical data collected at the site of the preliminary medical exam for all asylum seekers at the Charité - Universitätsmedizin Berlin suggest a different trend. COVID-19 infections have become prevalent in this population – what factors lead to an increased risk of contamination are however not well understood. Exploring both the frequency and the risk factors for an infection within this vulnerable population may help formulate improved hygienic and medical concepts for infection protection.

Who can participate?
All refugees who seek asylum in Berlin receive a mandatory medical exam upon their arrival. All refugees (aged 18 and over) who present themselves for the exam are invited to participate in the study.

What does the study involve?
The study involves a blood sample and the completion of a questionnaire. The questionnaire includes items regarding the participant’s current and past (COVID-19 associated) symptoms; past SARS-CoV-2 test history; travel and hygiene conditions during the past 2 weeks as well as information regarding the individual's transit from their country of origin to Germany (including transportation method, stopovers in other countries, as well as the number and age of other travellers etc). The participant also agrees that routine data (including PCR test results)

collected by medical and administrative staff are matched using a pseudonym and integrated into the study's dataset.

What are the possible benefits and risks of participating?
While infection with SARS-CoV-2 can lead to potentially life-threatening COVID-19 disease, including acute respiratory distress as well as possible long-term complications, an infection can also remain asymptomatic and therefore unnoticed. Emerging research suggests that even individuals with an asymptomatic infection may be at risk for long-term implications including abnormalities of the lungs and heart. Consequences for others due to possible, unrecognized chains of transmission also pose a large risk.
Participants of the study are given the opportunity to receive the results of their blood sample. This way, they gain insight into their history of infection and possible time-limited protection against a recurring infection. This knowledge can add to the participant's knowledge of their personal health and medical history and can dissipate psychological and social pressure to a certain extent.
Issues or risks are not expected to occur due to study participation. Blood is sampled by experienced medical professionals during a routine medical consultation. This procedure is typically carried out without any complications.

Where is the study run from?
Data is collected in the Erstaufnahmeuntersuchungsstelle Reinickendorf (Medical Examination Centre of the Charité, located in Reinickendorf in Berlin) and in the Landesamt für Flüechtlingsangelegenheiten (State Authority and Registration Centre and for Asylum Seekers in Berlin). Study coordination is based in the Medical Directorate of the Charité Berlin (Germany).

When is the study starting and how long is it expected to run for?
January 2021 to June 2021

Who is funding the study?
The study is part of a larger research network (B-FAST) which targets a multitude of aspects relating to the testing and surveillance of the ongoing COVID-19 Pandemic. B-FAST is the joint research project run by a national alliance of medical universities in Germany funded by the Federal Ministry of Education and Research (Bundesministerium für Bildung und Forschung).

Who is the main contact?
PD Dr. Joachim Seybold MBA, joachim.seybold@charite.de

Contact information

Type(s)
Scientific

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
Nil known

Study information

Scientific Title
Prevalence and flight-associated risk factors of COVID-19 infection experienced by refugees: acute infections and seroprevalence of the SARS-CoV-2 virus in a population of asylum seekers arriving at the medical examination centre for refugees based in Berlin

Acronym
RiCOVeR

Study objectives
Displaced individuals are thought to be especially vulnerable to infection with SARS-CoV-2. Frequent lack of medical care during transit and overcrowding in refugee camps may aggravate both infection rates and symptom severity. However, little data exist regarding the prevalence of SARS-CoV-2 within this population. The Medical Examination Centre based in the Charité - Universitätsmedizin Berlin runs mandatory medical exams and primary treatment for all asylum seekers arriving in the German capital. It provides an optimal setting for the screening of refugees for past and acute COVID-19 infections. Due to the exploratory nature of the study, four explorative research questions were established to guide the data collection and analysis:

1. What is the prevalence of acute SARS-CoV-2 infections in a population of refugees at the time of their arrival at the Medical Examination Centre based in the Charité?
2. What is the prevalence of SARS-CoV-2 antibodies in a population of refugees at the time of their arrival at the Medical Examination Centre based in the Charité?
3. Are certain risk factors (age, country of origin, length of transit/migration, condition of shelter etc.) associated with higher rates of a) an acute SARS-CoV-2 infection and b) a positive SARS-CoV-2 antibody status?
4. Which symptoms do refugees who test positive for a SARS-CoV-2 infection report upon arrival at the Medical Examination Centre?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 05/03/2021, Ethics Committee of the Charité - Universitätsmedizin Berlin (Geschäftsstelle Ethikkommission, Charitéplatz 1, 10117 Berlin, Germany; +49 (0)30 450 517 222; ethikkommission@charite.de), ref: 400460

Study design
Observational cross-sectional cohort study

Primary study design
Observational

Study type(s)
Screening

Health condition(s) or problem(s) studied
COVID-19 (SARS-CoV-2 infection)

Interventions
All refugees who wish to seek asylum in Berlin receive a mandatory preliminary medical exam upon their arrival in the registration center. This exam consists of triage and first aid, documentation of chronic health conditions, a screening for tuberculosis as well as a check of the immunization status of each refugee. Since June 2020, all refugees undergo a mandatory PCR swab to test for acute SARS-CoV-2 infections. Individuals are only allowed to continue the registration of their request for asylum if the test returns negative.

Upon their agreement to take part, study participants are required to complete a questionnaire (with the help of the present doctors and translators). The questionnaire is split into two thematic dimensions: Part A focuses on the individuals' symptomatology, hygienic behavior, past COVID-19 testing and education status. Part B focuses on the individuals' travel route, transits and origin. Blood will also be sampled by medical staff at the Medical Examination Centre. Individuals are informed that their medical, routine and study data collected during both the exam and during their registration with the Landesamt für Flüchtlingsangelegenheiten (LAF) are matched using a pseudonym. The LAF is the authority responsible for the registration of all asylum applications and decides on an individual's rights for financial and social help after arriving in Berlin.

Information regarding the participants' transit to Germany and health status will be explored in order to determine possible correlations with a positive sample.

Intervention Type
Other

Primary outcome(s)
Infection with SARS-CoV-2 measured via a PCR test for acute infections and via a blood sample for the identification of past infections and the development of specific antibodies. The tests occur during the participants' routine medical exam at the Medical Examination Centre.

Key secondary outcome(s))
1. Current and past COVID-19 symptoms measured using questionnaire items posed by medical staff during the routine consultation

2. Hygiene and living conditions of the past 2 weeks measured using questionnaire items posed by medical staff during the routine consultation
3. Level of education measured using questionnaire items posed by medical staff during the routine consultation
4. Results of SARS-CoV-2 antigen rapid tests (nasopharyngeal swab) carried out prior to the medical exam by the Deutsches Rotes Kreuz (DRK). The DRK is a medical first-aid service responsible for antigen rapid tests screening upon arrival of refugees before registration begins
5. Transit and travel route of the asylum seekers apprehended using questionnaire items posed by translators at the Landesamt für Fluechtlingsangelegenheiten (LAF) after the routine consultation. The LAF is the state authority responsible for coordinating the registry of asylum seekers and their eligibility for financial, social and medical support in Berlin
6. Routine medical data (age, gender, tuberculosis status, pregnancy, allergies etc) collected during the medical consultation carried out by the staff of the Medical Examination Center

Completion date
30/06/2021

Eligibility

Key inclusion criteria
1. Participants aged 18 years and older
2. Participants seeking asylum in Berlin

Participant type(s)
Other

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Total final enrolment
1041

Key exclusion criteria
There are no specific exclusion criteria. If patients of the Medical Examination Centre do not wish to take part in the study, neither blood is sampled nor is the questionnaire (Part A and B) filled out and the routine exam is continued normally.

Date of first enrolment
24/03/2021

Date of final enrolment

15/06/2021

Locations

Countries of recruitment
Germany

Study participating centre
Charité Universitätsmedizin Berlin
Campus Mitte
Charitéplatz 1
Berlin
Germany
10117

Sponsor information

Organisation
Federal Ministry of Education and Research

ROR
https://ror.org/04pz7b180

Funder(s)

Funder type
Government

Funder Name
Bundesministerium für Bildung und Forschung

Alternative Name(s)
Federal Ministry of Research, Technology and Space, Bundesministerium für Bildung und Forschung, Federal Ministry of Education and Research, BMBF

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location

Germany

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated and/or analyzed during the current study will be available upon request from Dr Joachim Seybold (principal investigator, joachim.seybold@charite.de), only after the individual provides an abstract, describing their research objective that is related to the data. After approving the abstract, the data will be provided.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		12/06/2023	29/06/2023	Yes	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes