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Study of the spread of COVID-19 in St Petersburg, Russia

Submission date
26/05/2020

Recruitment status
No longer recruiting

Registration date
28/05/2020

Overall study status
Completed

Last Edited
14/06/2023

Condition category
Infections and Infestations

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

Plain English summary of protocol

Background and study aims
COVID-19 is a condition caused by the coronavirus (called SARS-CoV-2) that was first identified in late 2019. This virus can infect the respiratory (breathing) system. Some people do not have symptoms but can carry the virus and pass it on to others. People who have developed the condition may develop a fever and/or a continuous cough among other symptoms. This can develop into pneumonia. Pneumonia is a chest infection where the small air pockets of the lungs, called alveoli, fill with liquid and make it more difficult to breathe.
In 2020, the virus has spread to many countries around the world and neither a vaccine against the virus or specific treatment for COVID-19 has yet been developed. As of April 2020, it is advised that people minimize travel and social contact, and regularly wash their hands to reduce the spread of the virus.
Groups who are at a higher risk from infection with the virus, and therefore of developing COVID-19, include people aged over 70 years, people who have long-term health conditions (such as asthma or diabetes), people who have a weakened immune system and people who are pregnant. People in these groups, and people who might come into contact with them, can reduce this risk by following the up-to-date advice to reduce the spread of the virus.
As of late May 2020, Russia is one of the countries with the highest number of registered COVID-19 cases. Surveillance of specific antibodies (immunity) present in the blood will enable researchers to infer the extent of infection and its prevalence in the study population. The aim of this study is to estimate the prevalence of COVID-19 using blood tests for immunity, that will determine if the person was infected or not. This study also aims to determine the time period when this immunity lasts.

Who can participate?
At least 1000 individuals, 18 years old and older, both genders, will be invited at random. In this study, volunteers are not recruited, but are invited randomly from the population of St Petersburg. Random sampling is performed by a survey company on the list of mobile phone numbers with designated geography prefixes of St Petersburg.

What does the study involve?
This study involves an individual invitation to the clinic by mobile phone, one phone-based survey (takes about 10 minutes to complete), one paper-based survey (takes about 15-20

minutes to complete). The questionnaire for the computer-assisted telephone interview includes travel history, medical history, and socioeconomic status of the respondents. Sampled individuals are then invited to the clinic for blood sampling, their refusal to participate is recorded. Participants complete additional questionnaires in the clinic providing information on their medical history, history of allergies, chronic disease, smoking, and medication taken regularly. Contact tracing data and environmental conditions of the household are recorded. The study involves blood samples collected from the vein and then testing for SARS-CoV-2-specific antibodies.

What are the possible benefits and risks of participating?
There are no clear benefits for the participants of the study. No clinical decision is made based on the test result. The knowledge of prior COVID-19 is acquired but it cannot be interpreted as immunity against future SARS-CoV-2 infection. In general, participants will contribute to the knowledge of disease spread and immune response dynamics. Blood sampling is a procedure that involves skin puncture and may be uncomfortable, it can cause mild bruising, and in rare cases infections. However, serious adverse events associated with this procedure are extremely rare.

Where is the study run from?
Clinic “Scandinavia” (LLC Ava-Peter) (Russia)

When is the study starting and how long is it expected to run for?
April 2020 to October 2020

Who is funding the study?
1. European University at Saint Petersburg (Russia)
2. Clinic “Scandinavia” (LLC Ava-Peter) (Russia)

Who is the main contact?
Dr Dmitriy Skougarevskiy
dskougarevskiy@eu.spb.ru

Contact information

Type(s)
Scientific

Contact name
Dr Dmitriy Skougarevskiy

ORCID ID
http://orcid.org/0000-0002-4022-6210

Contact details
6/1A Gagarinskaya ul.
St. Petersburg
Russian Federation
191187
+7 (0)8123867637
dskougarevskiy@eu.spb.ru

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
NCT04406038

Secondary identifying numbers
CDRU-001

Study information

Scientific Title
A population-based seroprevalence of SARS-CoV-2-specific antibodies among adults in St Petersburg, Russia: a longitudinal cohort study

Study objectives
This is an observational epidemiological study seeking to evaluate the spread and dissemination of SARS-CoV-2 in a major Russian city with alleviated sample selection problems arising out of volunteer bias in the midst of the pandemic.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Approved 20/05/2020, Commission on Academic Planning of the European University at St Petersburg (6/1A Gagarinskaya ul., 191187 St Petersburg, Russia; no tel; knp@eu.spb.ru), no ref
2. Approved 26/05/2020, Local Ethics Committee of Scandinavia clinic (LLC AVA-PETER, 4 korp. 1 Ilushina ul., 197372 St Petersburg, Russia; +7 (0)8126007870; Udina-NM@avaclinic.ru), no ref

Study design
Observational longitudinal cohort study

Primary study design
Observational

Secondary study design
Cohort study

Study setting(s)
Other

Study type(s)
Screening

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

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

Interventions
Clinically asymptomatic adults are sampled from the population using random digit dialing and tested for the presence of SARS-CoV-2-specific antibodies in the blood serum. Additional data is collected on travel history, medical history, and socio-economic status of participants.

Intervention Type
Other

Primary outcome measure
Current primary outcome measure as of 14/08/2020:
Prevalence of the SARS-COV-2 infection in St Petersburg, Russia measured by SARS-CoV-2–specific antibodies serial testing (Abbott Architect SARS-CoV-2 IgG) and adjusted for volunteer bias and test validity (sensitivity and specificity). The prevalence is measured at the baseline and every 2 weeks from the start of the trial, each measurement spans 4 weeks.

Previous primary outcome measures:
Prevalence of the SARS-COV-2 infection in St Petersburg, Russia measured by SARS-CoV-2–specific antibodies serial testing (Abbott Architect SARS-CoV-2 IgG) and adjusted for volunteer bias and test validity (sensitivity and specificity). The prevalence is measured at the baseline and every 2 weeks from the start of the trial for 18 weeks.

Secondary outcome measures
Current secondary outcome measures as of 14/08/2020:
1. Adjusted prevalence odds ratios by sex and age groups, socioeconomic status measured at the baseline and every 2 weeks from the start of the trial, each measurement spans 4 weeks
2. Cumulative seropositivity, seroreversion and seroconversion measured using Abbott Architect SARS-CoV-2 IgG at the baseline and every 2 weeks from the start of the trial, each measurement spans 4 weeks, and by the end of the study

Previous secondary outcome measures:
1. Adjusted prevalence odds ratios by sex and age groups, socioeconomic status measured at the baseline and every 2 weeks since the start of the trial for 18 weeks
2. Cumulative seropositivity, seroreversion and seroconversion measured using Abbott Architect SARS-CoV-2 IgG at the baseline and every 2 weeks since the start of the trial for 18 weeks and by the end of the study
3. Antibody dynamics: mean geometric titers of antibodies IgG measured using Abbott Architect SARS-CoV-2 IgG at the baseline and every 2 weeks since the start of the trial for 18 weeks and by the end of the study

Overall study start date
29/04/2020

Completion date
28/10/2020

Eligibility

Key inclusion criteria
1. Individuals sampled from the population of St Petersburg, Russia using random digit dialling
2. Aged 18 and older of both genders
3. Asymptomatic at the time of blood draw
4. Written informed consent for a blood draw, SARS-COV-2 antibody test, and data collection

Participant type(s)
All

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
1000

Key exclusion criteria
1. Presence of fever or cough or respiratory distress at the time of blood test not attributable to other known chronic disease
2. Age under 18
3. Any health condition that may be a contraindication towards blood sampling in outpatient clinic
4. Residence in Kolpinskiy, Kurortniy, Krasnoselsky, Kronshtadtskiy, Petrodvorcoviy, Pushkinskiy districts of St Petersburg

Date of first enrolment
27/05/2020

Date of final enrolment
10/06/2020

Locations

Countries of recruitment
Russian Federation

Study participating centre
Clinic “Scandinavia”
Moskovskiy pr., 73/4

St Petersburg
Russian Federation
196084

Sponsor information

Organisation
European University at Saint Petersburg

Sponsor details
6/1A Gagarinskaya ul
Saint Petersburg
Russian Federation
191187
+7 (0)8123867637
rectors_office@eu.spb.ru

Sponsor type
University/education

Website
https://eusp.org/en/

ROR
https://ror.org/04p2rkp70

Funder(s)

Funder type
University/education

Funder Name
European University at Saint Petersburg

Funder Name
Clinic “Scandinavia” (LLC Ava-Peter)

Results and Publications

Publication and dissemination plan

The researchers intend to submit the results from the first wave of the study to a peer-reviewed public health journal within 1 month after completion of participant recruitment. They intend to submit the results of the cohort study within 5 months of the overall trial end date.

Intention to publish date
10/07/2020

Individual participant data (IPD) sharing plan
Anonymized individual-level phone survey data and paper-based survey data, anonymized test results, and analytic code are available in a designated repository at https://github.com/eusporg/spb_covid_study20 under Creative Commons License Attribution 4.0 International (CC BY 4.0) license.

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version V2	15/07/2020	14/08/2020	No	No
Preprint results	non-peer-reviewed results in preprint	04/11/2020	16/03/2021	No	No
Dataset			14/06/2023	No	No
Results article		12/06/2021	14/06/2023	Yes	No
Results article		21/06/2021	14/06/2023	Yes	No
Results article		15/06/2022	14/06/2023	Yes	No
Results article		22/09/2022	14/06/2023	Yes	No