ISRCTN18181860 https://doi.org/10.1186/ISRCTN18181860

Corona Immunitas: a nationwide program of antibody studies of SARS-CoV-2 in the Swiss population

Submission date
09/07/2020

Recruitment status
No longer recruiting

Registration date
13/07/2020

Overall study status
Completed

Last Edited
29/08/2023

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

The increasing number of persons diagnosed with a SARS-CoV-2 infection in February and March 2020 and the subsequent Swiss Federal Council's measures had major implications for public life and for the economy. For guidance after these measures have lifted and for future policy decisions on how to minimize the disease and societal burden of SARS-CoV-2 reliable epidemiological data is needed. The knowledge of the nation-wide prevalence of SARS-CoV-2 infection at the level of the population, in different geographical areas and of specific age groups is required. This knowledge will also help prepare future outbreak responses and is important to inform future vaccination strategies.

In a number of Swiss Cantons, studies on the seroprevalence of SARS-CoV-2 antibodies and the extent and duration of immunity are planned or have already started. The interest for such epidemiological studies comes from both Cantonal authorities and scientists who want to learn about the seroprevalence of SARS-CoV-2 antibodies, both in the general population (across age ranges) and in specific groups of persons (e.g. nursing home residents, working in specific sectors of economy, from citizens, etc.).

The scientists of the Swiss School of Public Health (SSPH+) have agreed to coordinate their effort in order to make their data as comparable as possible, to create synergies and reduce redundancies. The goal is to make the studies informative for policy makers on the national and Cantonal level while fully respecting the autonomy of the Cantons and scientists involved. SSPH+ is committed to shed light on the extent of the spread of SARS-CoV-2, as quickly as possible, in Switzerland, and has launched an initiative with the aim of acquiring funding from public and private sources (https://www.corona-immunitas.ch/).

The aim of this study is to determine the extent and nature of infection with SARS-CoV-2 in the general population and in specific subgroup in different Cantons of Switzerland, after the first major wave and in further epidemic phases of SARS-CoV-2, and to contribute to consistent estimates in the Swiss population.

Who can participate?
All persons who are invited to participate in the study (randomly selected participants from the general population and specific sub-populations).

What does the study involve?
Study participation includes 1) the completion of the baseline questionnaire; 2) the collection of a peripheral blood sample by venipuncture for determination of SARS-CoV-2 antibodies at a study center, a mobile unit or the participant's home; and 3) the invitation to fill-in a weekly and monthly digital follow-up questionnaire for the next 6 to 12 months.
Specific sub-populatiopns of participants will be re-invited for repeated blood collection for SARS-CoV-2 antibody tests, where the same procedures will be used.

What are the possible benefits and risks of participation?
The primary benefit of the study is indirect. The evaluation of the SARS-Cov-2 seroprevalence in the general population and specific subgroups is essential to understand what phase of the epidemic we are currently in, to be able to make predictions for the continuation of the epidemic and to put in place adequate public health measures. It will also provide information on the proportion of oligo- and asymptomatic cases. The publication of these results as open access will be useful to the entire international scientific community as well as other stakeholders including guideline developers, policy makers and physicians.

The risk associated with the collection of blood samples is very low. Possible complications are minor and include a hematoma at the puncture site, infection, or vagal discomfort during blood collection. All safety measures will be taken to prevent these complications from occurring by adopting standard collection rules and working with registered nurses. There is also a risk of SARS-CoV-2 infection on the way from participants' homes to the study centers and during contact at the study site. We have tried to minimize this risk; during all interactions, study staff will follow current standard hygiene procedures (hand washing and disinfection procedures, wearing masks and gloves) and participants will wear a mask, provided by the study staff. The mobile investigation teams who travel to conduct the study visit at the participants' home will follow the same procedures.

Where is the study run from?
Swiss School of Public Health (SSPH+), an inter-university faculty that unites twelve Swiss universities, coordinates nationwide the seroprevalence studies. The responsible study centers in the participating Swiss Cantons run the studies.

When is the study starting and how long is it expected to run for?
March 2020 to April 2023

Who is funding the study?
Corona Immunitas is funded by several sources: All: by fundraising of SSPH+ that includes funds of the Federal Office of Public Health and private funders (foundations, companies and private donations; ethical guidelines for funding stated by SSPH+ will be respected); center specific by funds of the Cantons, by institutional funds of the Universities and by other center-specific sources.

Who is the main contact?
Prof. Dr. med. et phil. Milo A. Puhan, miloalan.puhan@uzh.ch

Study website
https://www.corona-immunitas.ch/

Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
Nil known

Study information

Scientific Title
Seroprevalence of SARS-CoV-2 antibodies and development of immunity in the Swiss population – Multicenter population-based observational studies to inform policy making

Acronym
Corona Immunitas

Study objectives
The main goal of the Corona Immunitas research program is to determine the extent and nature of infection with SARS-CoV-2 in all regions of Switzerland in a highly consistent and comprehensive way in the general Swiss population as well as particularly exposed and vulnerable groups. Specific aims are to: 1) quantify the number of individuals infected with SARS-CoV-2 in the population with or without symptoms at several points in time; 2) compare the seroprevalence between the general population and specific subpopulations; 3) investigate the nature and extent of immunity after infection; 4) assess the association between participant characteristics and behaviors with infection; and 5) quantify the impact of the pandemic on mental and physical health. Most importantly, this evidence-based program aims to provide policy-makers and other decision makers with important evidence for deciding which public health and setting-specific measures to implement or lift for the general population and specific subpopulations at different points in time.

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 28/05/2020, Cantonal Ethics Committee Zurich (Stampfenbachstrasse 121, CH-8090 Zurich, Switzerland; +41 43 259 79 70; Info.KEK@kek.zh.ch), ref: 2020-01247

Study design
Cross-sectional and longitudinal studies in the general population and in specific subpopulations with serological testing at baseline and a digital-only or combined digital and serological follow-up

Primary study design
Observational

Secondary study design
Cross-sectional and longitudinal

Study setting(s)
Community

Study type(s)
Diagnostic

Participant information sheet
See additional files

Health condition(s) or problem(s) studied
SARS-CoV2 infection (COVID-19)

Interventions
Potential participants are either randomly selected from the general population or selected from specific sub-population settings. The process of enrollment is organized by each study center and for each population individually. Generally, potential participants are informed and invited to participate in the study by postal mail or email and asked to schedule an appointment for a study visit either at a study center, at a mobile unit (bus) or at their home (vulnerable persons). Before the study visit, participants are provided with the link to an online baseline questionnaire asking demographic questions, symptoms, other tests taken for SARS-CoV-2, preventative measure behaviors and quality of life measures.

After providing informed consent, the study visit is conducted by trained study personnel. The expected duration of the visit is 20-30 minutes in total and data is assessed in three stages:
1. Study staff checks the completeness of the baseline questionnaire and, if incomplete, advises the participant to complete it on a computer, tablet or on paper/pencil.
2. Trained health care staff collects a peripheral blood sample by venipuncture for the determination of SARS-CoV-2 antibodies (quantity varies according to study site). The participants are explained orally and by a leaflet how to interpret a positive serological test result (probability that result is inaccurate) and are instructed to keep on following the recommendations of the public health authorities, regardless of their individual test result. The entire sequence from blood withdrawal to storage and testing follows a Standardized Operating Procedure.
3. Participants are invited to fill in a weekly and monthly digital follow-up questionnaire for the next 6 to 12 months, capturing health status, symptoms and behaviors over time.

Specific groups of participants will be re-invited for repeated blood collection for SARS-CoV-2 antibody testing, once or several times.

Intervention Type
Other

Primary outcome measure
Seroprevalence of SARS-CoV-2 antibodies measured using peripheral blood sample by venipuncture in the general population and in specific subpopulations at repeated time points during the epidemic in Switzerland

Secondary outcome measures
1. Presence of symptoms suggestive of a common cold, influenza and similar upper respiratory tract infections prior to the first study visit. Measured by baseline questionnaire (at baseline)
2. Potential risk factors and preventive measures for SARS-CoV-2 infection (exposure, socio-economic factors, adherence to general hygiene and physical distancing rules, utilization of mask and gloves). Measured by baseline questionnaire (at baseline)
3. Incidence of self-reported symptoms and SARS-CoV-2 infections after the first study visit in initially seropositive individuals (extent and duration of immunity after infection with SARS-CoV-2). Measured by digital follow-up questionnaire (weekly)
4. Proportion of seronegative individuals of the first investigation wave who will self-report symptoms and infection with SARS-CoV-2. Measured by digital follow-up questionnaire (weekly)
5. Course over time in access to health care, health care renunciation, going outside (frequency, reason, physical activity), preventive measures with respect to COVID-19. Measured by digital follow-up questionnaire (weekly and monthly)
6. Course over time in mental well-being, specifically stress, anxiety and depression. Measured by digital follow-up questionnaire (monthly)

Overall study start date
18/03/2020

Completion date
31/03/2023

Eligibility

Key inclusion criteria
1. No acute SARS-CoV-2 infection: no presence of symptoms for at least 48 hours
2. In case of a SARS-CoV-2 infection verified by a RT-PCR test, the earliest inclusion is 21 days after the test date

Participant type(s)
All

Age group
All

Sex
Not Specified

Target number of participants
In the frame of Corona Immunitas, it is planned to include around 25,000 participants in the different Cantons / centers of Switzerland.

Total final enrolment
28000

Key exclusion criteria
1. No informed consent
2. Suspicion of acute COVID-19 infection

Date of first enrolment
01/04/2020

Date of final enrolment
31/12/2022

Locations

Countries of recruitment
Switzerland

Study participating centre
University of Zurich
Epidemiology, Biostatistics and Prevention Institute
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8001

Study participating centre
University of Fribourg
Population Health Laboratory
Department of Community Health
Faculty of Science and Medicine
Route des Arsenaux 41
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1700

Study participating centre
Università della Svizzera Italiana
Institute of Public Health
Via G. Buffi 13
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Study participating centre
Unisanté Lausanne
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Avenue des Casernes 2
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Study participating centre
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1205

Study participating centre
Swiss Tropical and Public Health Institute
Department of Epidemiology and Public Health
Socinstrasse 57
Basel
Switzerland
4051

Study participating centre
Service cantonal de la Santé Publique de Neuchâtel
Beaux-Arts 13
Neuchâtel
Switzerland
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Study participating centre
Zürcher Hochschule für Angewandte Wissenschaften (ZHAW)
Departement Gesundheit
Forschungsstelle Gesundheitswissenschaften
Katharina-Sulzer-Platz 9

Winterthur
Switzerland
8400

Study participating centre
Kantonsspital St. Gallen
Klinik für Infektiologie und Spitalhygiene
Rorschacherstrasse 95
St. Gallen
Switzerland
9007

Study participating centre
Kantonsspital Graubünden
Loestrasse 170
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Study participating centre
Universität Bern
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Mittelstrasse 43
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Study participating centre
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Study participating centre
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Study participating centre
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Sponsor information

Organisation
Swiss School of Public Health

Sponsor details
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Sponsor type
University/education

Website
https://ssphplus.ch/

ROR
https://ror.org/01czqbr06

Funder(s)

Funder type
Government

Funder Name

Fundraising of SSPH+ that includes funds of the Bundesamt für Gesundheit (Federal Office of Public Health, Switzerland)

Funder Name
Fundraising of SSPH+ that includes funds of private funders (ethical guidelines for funding stated by SSPH+ are respected)

Funder Name
Center specific: Institutional funds and funds provided by the Cantons (public funds)

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
30/06/2023

Individual participant data (IPD) sharing plan
The de-identified individual participant data generated during the current study are available upon request. Data access guidelines, database documentation and description are provided in Zenodo:
1. Corona Immunitas Phases 1 to 4 - Central Database: https://zenodo.org/record/7520050
2. Corona Immunitas Phases 5 and 6 - Central Database: https://zenodo.org/record/7520125

IPD sharing plan summary
Stored in publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	early results	01/08/2020	09/07/2020	Yes	No
Participant information sheet	version v4	11/06/2020	07/08/2020	No	Yes
Protocol article	protocol	01/12/2020	26/10/2020	Yes	No
Results article	Seroprevalence and attitudes of care home and in-home care staff	16/03/2022	18/03/2022	Yes	No
Results article	Results from the Swiss national seroprevalence study Corona Immunitas	20/06/2022	21/06/2022	Yes	No
Results article	Association of plasma zinc levels with anti-SARS-CoV-2 IgG and IgA seropositivity in the general population: A case-control study	18/04/2023	03/05/2023	Yes	No

Results article	Recovery and symptom trajectories up to 2 years after SARS-CoV-2 infection	31/05/2023	01/06/2023	Yes	No
Dataset	Corona Immunitas Phases 1 to 4 - Central Database	26/04/2023	29/08/2023	No	No
Dataset	Corona Immunitas Phases 5 and 6 - Central Database	26/04/2023	29/08/2023	No	No
Other publications	Protocol and initial results of Corona Immunitas Digital Follow-Up eCohort	28/02/2022	29/08/2023	Yes	No
Results article	Association between serologically confirmed COVID-19 infection and cognitive functioning in community dwelling older adults	21/03/2023	29/08/2023	Yes	No
Results article	Changes in socioeconomic resources and mental health after the second COVID-19 wave	23/03/2023	29/08/2023	Yes	No
Results article	Functional immunity against SARS-CoV-2 in the general population after a booster campaign and the Delta and Omicron waves	01/08/2022	29/08/2023	Yes	No
Results article	Impact of screen time and green time on mental health in children and adolescents during the COVID-19 pandemic	01/08/2022	29/08/2023	Yes	No
Results article	Longitudinal humoral and cell-mediated immune responses	01/08/2023	29/08/2023	Yes	No
Results article	Prevalence and association of frailty with SARS-CoV-2 infection in older adults	12/01/2023	29/08/2023	Yes	No
Results article	SARS-CoV-2 infection among employees working from home and on site	16/09/2022	29/08/2023	Yes	No
Results article	SARS-CoV-2 seroprevalence and COVID-19 disease among people on opioid agonist treatment	12/01/2022	29/08/2023	Yes	No
Results article	Seroprevalence trends of anti-SARS-CoV-2 antibodies and associated risk factors	04/03/2023	29/08/2023	Yes	No
Results article	Trajectories of depression, anxiety and stress during the pandemic	01/05/2022	29/08/2023	Yes	No
Results article	Vaccination intention, beliefs, attitudes, and trust	23/03/2022	29/08/2023	Yes	No