ISRCTN91064601 https://doi.org/10.1186/ISRCTN91064601

Presence of antibodies in children and young adults living with at least one SARS-CoV-2 positive person

Submission date
16/10/2020

Recruitment status
No longer recruiting

Registration date
16/12/2020

Overall study status
Completed

Last Edited
25/03/2021

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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 March 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.

Children appear to be less vulnerable to coronavirus and particular attention must be paid to family clusters. The aim of this study is to evaluate young people aged between 4 and 16, belonging to families with at least one positive swab result for this virus.

Who can participate?
Young people aged 4 to 16 years, who live with at least one person who has tested positive for SARS-CoV-2 infection.

What does the study involve?
The study involves a preliminary phone interview and subsequently a test for the detection of antibodies for SARS-CoV-2.

What are the possible benefits and risks of participating?
None. This study could be useful for the participants and for the whole community to gain information about their health condition and the impact of COVID-19 on children.

Where is the study run from?
University of Milan (Italy)

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

Who is funding the study?
University of Milan (Italy)

Who is the main contact?
Prof. Giampetro Farronato, giampietro.farronato@unimi.it)
Prof. Gianluca Tartaglia, gianluca.tartaglia@unimi.it

Contact information

Type(s)
Scientific

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Type(s)
Public

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CE15052020

Study information

Scientific Title
Evaluation of the serological profile of subjects aged between 4 and 16 years old with at least one SARS-CoV-2 positive cohabitant: a randomized clinical trial

Study objectives
Children aged between 4 and 16 years with at least a positive cohabitant are less vulnerable to covid infection than adults

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 18/06/2020, Università degli Studi di Milano (Via Carducci 18, Milano CAP 20129, Italy; +39 (0)254100378; firm@tascalawfirm.com), ref: IRB15052020

Study design
Observational cross sectional

Primary study design
Observational

Secondary study design
Cross sectional study

Study setting(s)
Community

Study type(s)
Screening

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
Detection of IgG and IgM antibodies for Sars-Cov-2 in children aged between 4 and 16 years

Interventions
Families interviewed by telephone to gather information about the family cluster (i.e. age and number of cohabitants, their symptoms and swab results, if performed), the positive subject (i.e. sex, age, risk exposure during the lockdown, course of the disease, symptoms suggestive of COVID-19) and children aged between 4 and 16 y.o. (i.e. sex, age, risk exposure during the lockdown, drug therapy and/or chronic diseases, symptoms suggestive of COVID-19)

Children undergo a rapid lateral flow chromatographic test for the detection of IgG and IgM antibodies for Sars-Cov-2

Intervention Type
Other

Primary outcome measure
Presence of IgG and IgM antibodies for Sars-Cov-2 using a rapid lateral flow chromatographic test at a single time point.

Secondary outcome measures
1. Age measured at the time of serological test
2. Days from negativization measured at the time of serological test (measured by asking the positive subject for the date of certified negativization [after two negative swabs])

Overall study start date
15/03/2020

Completion date
06/08/2020

Eligibility

Key inclusion criteria
1. Between 4 and 16 years old
2. At least one cohabitant with positive result of Sars-Cov-2
3. From the districts of Segrate (MI), Vimodrone (MI), Peschiera Borromeo (MI), Crema (CR), and Lodi (LO)

Participant type(s)
Healthy volunteer

Age group
Mixed

Sex
Both

Target number of participants
49

Total final enrolment
49

Key exclusion criteria
Does not consent to take part

Date of first enrolment
12/06/2020

Date of final enrolment
05/08/2020

Locations

Countries of recruitment
Italy

Study participating centre
University of Milan
Department of Biomedical, Surgical and Dental Sciences
Fondazione IRCCS Cà Granda Ospedale Maggiore Policlinico
via Francesco Sforza, 35
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Sponsor information

Organisation
University of Milan

Sponsor details
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Sponsor type

Hospital/treatment centre

Website
http://www.unimi.it/ENG/

ROR
https://ror.org/00wjc7c48

Funder(s)

Funder type
University/education

Funder Name
Università degli Studi di Milano

Alternative Name(s)
Universitas Studiorum Mediolanensis, University of Milan, La Statale, UniMi

Funding Body Type
Private sector organisation

Funding Body Subtype
Universities (academic only)

Location
Italy

Results and Publications

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

Intention to publish date
06/06/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available due to lack of consent to share.

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?

Results article	04/02/2021	25/03/2021	Yes	No