Corona Research Limburg

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Which determinants (risk exposure, symptoms, compliance with measures) are associated with a positive SARS-CoV-2 antibody test in inhabitants of the province of Limburg?

Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Viral infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON49431

Source
ToetsingOnline

Brief title
COL

Condition

- Viral infectious disorders

Synonym
Corona antibodies, SARS-CoV-2 antibodies

Research involving
Human

Sponsors and support

Primary sponsor: GGD Zuid Limburg
Source(s) of monetary or material Support: GGD;Provincie

Intervention

Keyword: Adults and older people, Antibodies, COVID-19, Determinants

Outcome measures

Primary outcome

The primary outcome measure of the study is the result of SARS-CoV-2 antibody

testing (positive or negative), based on total IgG (dichotomous value).

Secondary outcome

The IgG titre (continuous value).

Study description

Background summary

In March 2020, the World Health Organization (WHO) declared Europe as the epi centre of the new coronavirus (SARS-CoV-2) pandemic [1]. Within six weeks of the first reported confirmed corona patient in Europe, all 27 countries were affected. In the Netherlands, the first confirmed COVID-19 patient was reported on 27 February 2020 [2]. Limburg is one of the most severely affected provinces with 442 infections per 100,000 inhabitants on 5 Aug 2020 [3].
The spread of the virus slows down when (part of) the population develops immunity in a natural way [4]. The minimum proportion of people who must have developed immunity to SARS-CoV-2 to be able to speak of group immunity has been estimated at 67%, assuming that one infected person can infect two to three others on average [5]. Several studies are conducted to gain more insight into the obtained immunity against SARS-CoV-2 in the Dutch population (seroprevalence). The National Institute for Public Health and the Environment (RIVM) is currently conducting several studies. The RIVM previously investigated the presence of SARS-CoV-2 antibodies in fingerprint blood of 2,096 people [6]. Antibodies could be detected in 5.5%, with no difference being found between men and women. Individuals with antibodies against SARS-CoV-2 were more likely to have complaints such as reduced odour/taste, fever, general malaise, muscle pain and joint pain, compared to individuals without antibodies. RIVM is currently conducting a large-scale study into group immunity in a population of 6,000 Dutch people who previously participated in the Pienter Study [7]. In the Pienter study, SARS-CoV-2 antibodies will be determined using fingerprint blood too.
Finally, the RIVM, in collaboration with Sanquin, is investigating the extent to which the Dutch population has SARS-CoV-2 antibodies. However, this only concerns blood sample analysis and no additional data are collected [7]. Until now, further studies into the presence of SARS-CoV-2 antibodies in a blood sample obtained via venepuncture (seroprevalence) are lacking.

It is highly important to generate knowledge about the nature and determinants of the spread of SARS-CoV-2 in Limburg, a region severely affected by the COVID-19 pandemic. By researching determinants, we aim to generate knowledge about the occurrence per region, and in certain groups (e.g. old/young, male/female, chronically ill/not ill). We hope to gain more insight into why Limburg has been hardly affected by looking at possible risk exposure (e.g. attending an event, visiting choirs), relationship with border countries (e.g. possible exposure in Gangelt) etc. The results of the study will, in addition to providing insight, contribute to the more targeted deployment of COVID-19 measures in 2020.
Therefore, the aim of the study is to provide information about the determinants associated with the proportion of positive SARS-CoV-2 antibody tests in the Limburg population.

Study objective

Which determinants (risk exposure, symptoms, compliance with measures) are associated with a positive SARS-CoV-2 antibody test in inhabitants of the province of Limburg?

Study design

Cross-sectional
The study is a cross-sectional study with invasive measurements.

Duration
The study (the collection of materials and data) is expectedly conducted within a time frame of approximately 10 weeks.
However, the exact study duration depends on the number of respondents. The targeted number of respondents for this study is 10,000 people.

Recruitment
Recruitment takes place through open media channels, where we refer to the GGD website that contains all the relevant information on the study.

Enrolment
People who are potentially interested in participating in the study, can visit the GGD website where they find all the study information. The website also contains a weblink to register for the study after someone has had enough time to think about it. After registering, the person will receive an email with the detailed study information (including the Patient Information Letter). Also the person will be contacted by phone by our call-center (*mondeling*). At that moment, the study will be explained and the person can ask questions. Also at that moment, the enrolment visit is scheduled. Enrolment entails registration, information (written and by phone) and the informed consent procedure. The enrolment visit takes place at least two days after the study information had

been send to the person (by email).
A total of 10,000 people can be included in the research. After the first 10,000 persons have registered, i.e. they have registered for the study via the website, the registration will be closed. Other persons (up to 3,000) can then still apply for the reserve list. If a person (out of the original 10,000) does not wish to participate, the person who first registered for the reserve list will be contacted for enrolment.

Participation
Participants have registered to be potentially interested in participating in the study, they have been called (by the call-center) to schedule the enrolment visit (to provide informed consent and have their blood drawn for testing on SARS-Cov-2-antibodies. Participation starts with the blood drawing AFTER the participants provided written informed consent. When the participants provide consent, again they are given the opportunity to ask questions and participation eligibility will be checked. After the blood test, participants receive the online questionnaire (instructions are provided). A helpdesk is available to help fill in the questionnaire.

Blood test
Minimally two days after (usually this will be a few days later, depending on the logistics of the blood-sampling and staffing), blood is taken by venipuncture (10ml EDTA 1 tube) by trained and qualified staff, under the responsibility of the GGD.

Result
The blood-samples are tested batchwise in the laboratory of the MUMC+. The GGD will inform the participants of the results (positive or negative) via email. This means of communication allows for providing additional information and explanation on the interpretation of the blood-test, information about corona and other issues relevant for infection-prevention and public health.

Study burden and risks

This study is low risk.
The questionnaire is non-invasive, it costs some time to fill in (about 35-40 minutes).
The venipuncture is a minuma burden. It is being conducted by well-trained and qualified staff, under the responsibility of the GGD. The risk therefore is very small.
The participants receive the result of the corona-antibody test. Thet will be extensively informed about the interpretation of the test results.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

18 years or older
and capable to read the study information and fill in the questionnaire;
and willing to have their blood drawn for testing

Exclusion criteria

younger than 18 years of age
insufficienly capable to understand the Dutch language
unwilling to have blood drawn for antibody testing

Study design

Design

Study type: Observational invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	23-10-2020
Enrollment:	10000
Type:	Actual

Ethics review

Approved WMO

Date:	05-10-2020
Application type:	First submission
Review commission:	METC academisch ziekenhuis Maastricht/Universiteit Maastricht, METC azM/UM (Maastricht)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
CCMO	NL74791.068.20
Other	NTR ingediend, nummer NL8889