Seroprevalence of COVID-19 in hairdressers and catering staff (COcostudy)

Published: 11-06-2020 Last updated: 09-04-2024

Primary research goal- Evaluate whether resuming activities of hairdressers and catering staff results in a significantly higher percentage that produces antibodies against SARS-CoV-2 after 3 months.Secondary research goals- Identifying determinants...

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

Summary

ID

NL-OMON49337

Source ToetsingOnline

Brief title COco

Condition

• Viral infectious disorders

Synonym coronavirus, respiratory infection

Research involving Human

Sponsors and support

Primary sponsor: GGD West-Brabant

Source(s) of monetary or material Support: GGD West Brabant en de RIVM regiogelden. Mogelijk wordt nog verdere subsidie gevraagd. Dan zal het formulier weer aangepast worden.

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Intervention

Keyword: Cateringstaff, Hairdressers, SARS-CoV-2, Seroprevalence

Outcome measures

Primary outcome

Seroprevalence of SARS-CoV-2-antibodies at inclusion and three months later.

Secondary outcome

Seroprevalence of SARS-CoV-2-antibodies at 6 and 10 months,

cumulative incidence of seroconversion for SARS-CoV-2-antibodies,

sqRT-PCR-confirmed SARS-CoV-2-infection,

self-reported symptoms suspect for COVID-19,

hospitalization,

mortality

Study description

Background summary

On February 27th, 2020, the first Dutch patient was diagnosed with COVID-19, a SARSCoV-2 infection. The virus spread quickly and since than almost 6000 patients died from the effects of this infection, which is expected just the tip of the iceberg. At the end of April the first Dutch serological studies (PIENTER 3, Sanquin) were released. These studies reported an incidence rate of 3-4% among the Dutch population who had experienced the virus. The province of Noord-Brabant is the most severely affected Dutch province. It is expected that in the region West-Brabant about 5-10% of the population produced antibodies against COVID-19

Since the start of the outbreak in the Netherlands, various measures have been taken to reduce the spread in the population and to protect vulnerable people in particular. As a result, the reproduction number (R0) has fallen below 1 since the end of March, which means that the virus is extinguishing in the Netherlands. This means that the taken measures in place can be relaxed.

For example hairdressers and catering staff are allowed to return to work. However, little is known about the effect of easing these measures on Dutch society. The medical scientific literature focuses in particular on COVID-19 in critically ill patients admitted to hospital. Much remains unknown about asymptomatic infections and transmission in the general population and specific populations outside the hospital.

In the COco study, we investigate the consequences of resuming work on the risk of COVID-19 in hairdressers and catering staff, in the West Brabant region. Because the province of Noord-Brabant is the seat of the Dutch pandemic, this is a unique region to perform this study. The results of the COco study can be used for policy on this virus throughout the Netherlands.

In this study, GGD West-Brabant enters into a chain collaboration with Microvida (Breda), Amphi / University Nijmegen and Sanquin, and professional associations of hairdressers and catering staff are involved in the research.

Study objective

Primary research goal

- Evaluate whether resuming activities of hairdressers and catering staff results in a significantly higher percentage that produces antibodies against SARS-CoV-2 after 3 months.

Secondary research goals

- Identifying determinants (age, gender, function, co-morbidity, lifestyle, etc.) for antibody production against SARS-CoV-2.

Evaluate whether:

- there is a difference in antibody production between hairdressers and catering staff after resuming their activities.

- there is a difference in antibody production between personnel working in contact professions after resuming their activities and the general population of West Brabant, as tested by Sanquin.

- there is a difference in antibody production between staff working in contact professions after resuming their activities and hospital staff / professional football players.

- there are seasonal influences on the antibody production against SARS-CoV-2 in hairdressers and catering staff.

- Evaluate what percentage of patients afflicted with COVID-19 as measured by PCR produce detectable antibodies to SARS-CoV-2.

- Get a picture of the duration that antibodies (expected) remain measurable in the blood after initial detection.

Study design

The COco study is a prospective study. After inclusion, bloodsamples (3,5 ml) are taken from study participants to determine the seroprevalence at baseline (t0). In addition, baseline data is collected through a survey (age, gender, migration background, education level (socioeconomic status), lifestyle, function, complaints in the past three months, previously tested for SARS-CoV-2, measures taken by the employer to prevent spread of the virus, etc.). During the study period, participants keep a record of whether they have complaints that are appropriate for COVID-19, how much they have worked and, if applicable, with which protective measures. They also record whether they show risk behavior outside their work. If participants have complaints appropriate to COVID-19, they will be tested for SARS-CoV-2 by PCR from a throat and nasopharyngeal swab.

After 3 months (t1), another 3,5 ml of blood is taken to determine antibodies. This seroprevalence and sero incidence has been compared with the general population of West Brabant in collaboration with Sanquin, and with the hospital staff and professional football players in our region in collaboration with Prof. Kluytmans. Similar studies are performed in parallel in these populations, using the same serological assays, allowing reliable comparison.

Given the measures taken in our region and the period in which the study will start (summer period), we expect that after three months, about 10% of the West Brabant population will still have made antibodies against SARS-CoV-2. We consider it clinically relevant if this prevalence is 50% higher in our study population, i.e. 15%. With an alpha of 0.05 and power of 80%, we need to include 398 people in our study, 199 per group. We expect 10% failure. For catering staff we assume a dropout rate of 20%.

Hairdressers 10% dropout: 199 * 1.10 = 219 people Catering industry 20% dropout: 199 * 1.20 = 239 people

In addition, we expect that 8% of the people in contact professions already have antibodies, so they are not included in the incidence calculation.

Hairdressers: 219 / 0.92 = 238 Catering industry: 239 / 0.92 = 260 Total sample: 498

A third measurement will be carried out in December 2020 (t3). The purpose of this measurement is to measure the seasonal influences on antibody production against SARS-CoV-2. Because we expect that the antibody production in the West Brabant population has increased further with this measurement, a population of 498 people is sufficient, even with an increase in participants who drop out. If there is an indication of seasonal influence, a fourth measurement will follow in April 2021 (t3) to measure the antibody production again at the end of the "virus season". This is the case if the sero incident ratio (t1-> t2

versus t0 > t1) of our population is above 1.2.

Study burden and risks

Employees from the hairdressing and catering industry who participate in the COco study have a negligible risk and experience a minimal burden. In a period of maximum 10 months, a maximum of 5 hours of their time is requested. A blood sample of 3,5 ml is drawn up to 4 times. When a follow-up subject in the self-report indicates that he has symptoms suggesting a COVID-19 infection, a nasopharyngeal / throat swab is performed.

At the time of inclusion, a baseline questionnaire is completed that takes a maximum of 15 minutes from participants. In the following weeks, a short questionnaire (completion time: 5 minutes) is administered weekly, in which the experienced symptoms are also recorded.

Subjects do not experience any direct benefit from the study. Individual test results are made available to each subject during the study; results of the study will be summarized upon completion of the study.

Contacts

Public GGD West-Brabant

Doornboslaan 225-227 Breda 4816 CZ NL **Scientific** GGD West-Brabant

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Trial sites

Listed location countries

Netherlands

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Eligibility criteria

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

Inclusion criteria

Hairdressers and catering staff who are working in the hairdressing industry and catering industry. Working in North-Brabant, in Breda, Roosendaal and surroundings. At least work 100 hours in the hairdressing industry or in the catering industry in 3 months.

Exclusion criteria

Persons younger than 18 years Reluctant to blood draw Incapacitated or unwilling to give informed consent Blood or plasma donor at Sanquin

Study design

Design

Study type: Observational invasive		
Masking:	Open (masking not used)	
Control:	Uncontrolled	
Primary purpose:	Diagnostic	

Recruitment

NL	
Recruitment status:	Recruitment stopped
Start date (anticipated):	11-06-2020
Enrollment:	498
Туре:	Actual

Ethics review

Approved WMO	
Date:	11-06-2020
Application type:	First submission
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)
Approved WMO	
Date:	30-10-2020
Application type:	Amendment
Review commission:	MEC-U: Medical Research Ethics Committees United (Nieuwegein)

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 CCMO **ID** NL74225.100.20