Within household transmission of SARS-CoV-2 infections, a multicentre prospective cohort-study

Published: 06-04-2020
Last updated: 19-08-2024

Estimate key transmission parameters of SARS-CoV-2 in Europe from observing within household virus spread and seroconversion of household members, and to characterize the views and experiences of households regarding perceptions, practices regarding...

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

Summary

ID

NL-OMON52515

Source
ToetsingOnline

Brief title
CORONAhome

Condition

- Viral infectious disorders
- Respiratory tract infections

Synonym
Coronavirus infection, COVID-19

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: HORIZON 2020 vanuit RECOVER en VERDI

en eigen bijdrage UMCU en RIVM; substudy wordt gefinancierd door ZonMw

Intervention

Keyword: coronavirus, COVID-19, Household study, respiratory infections, SARS-CoV-2 reinfections

Outcome measures

Primary outcome

Estimate key transmission parameters of SARS-CoV-2 in Europe from observing

within household virus spread and seroconversion of household members.

o Household secondary attack rates

o Transmission rate

The secondary SARS-CoV-2 attack rate is defined as the number of secondary

cases divided by the number of household members at risk (i.e. excluding the

index case).

Substudy: Incidence rate of reinfections of SARS-CoV-2 and risk factors

associated with the incidence of SARS-CoV-2 reinfections (demographic,

clinical, virological and immunological).

Secondary outcome

Infer from the data the following transmission parameters:

o Incubation period

o Generation time

o Susceptibility and infectiousness of different types of individuals (e.g.

age, gender, disease severity, type of symptoms, viral load)

o Household (e.g. household size, living conditions, sanitary facilities, pets)

and behavioral characteristics that influence transmission

To characterize the views and experiences of households regarding perceptions, practices regarding infection control, and impacts of imposed isolation measures.

Describe clinical characteristics of mild/moderate SARS-CoV-2 infections that are detected during household follow-up and managed in community/ambulatory care.

Describe infection control practices and behaviors in affected households

Determine seroconversion rates during follow-up and how this compares with virologically confirmed SARS-CoV-2 infections

Understand the broader epidemiology of SARS-CoV-2 through studying asymptomatic individuals

Substudy: Incidence rate of (co-)infections (such as influenza viruses and RSV).

Study description

Background summary

SARS-CoV-2 outbreak was first reported in the city of Wuhan, China, on 31 December 2019 and was declared a Public Health Emergency of International Concern (PHEIC) by WHO on 30 January 2020. Because of the speed and scale of transmission of this emerging disease, the WHO declared the global COVID-19 outbreak has a pandemic on March 11th. Globally, more than 500.000 cases have now been reported to WHO from all continents. At the start of the pandemic, the number of cases reported outside China has increased almost 13-fold, and the number of affected countries expanded rapidly. On March 13th, the WHO declared that Europe is now the epicenter of the COVID-19 epidemic, with the largest number of cases reported from Italy.

In December 2021, the COVID-19 pandemic has again taken a new turn with the emergence of the Omicron Variant of Concern (VoC). This VoC, first detected in South Africa in November 2021, is characterized by a high number of mutations in immunodominant areas of the Spike protein. Preliminary results of in vitro immunological studies and epidemiological observations suggest that Omicron has increased transmissibility and/or a higher level of immune evasion from prior infection or vaccination, compared to Delta and other variants previously circulating. Further insight into the transmission characteristics emerging VoCs, and how this compares to the current epidemiology driven by infections with earlier variants, in populations with variable level of (vaccine) immunity is urgently needed to inform epidemic projections, mitigation policies including non-pharmaceutical interventions and vaccine (boosting) strategy.

Substudy:
Reinfections with SARS-CoV-2 occur frequently due to declining immunity after previous infection and/or vaccination and the emergence of new virus variants that partially circumvent existing immunity. Therefore, there remains a risk of new corona waves in the current phase of the Covid-19 pandemic, especially during the winter season. A better understanding of the longevity of protective immunity and the risk of reinfections, including their impact on individual health, allows improved preparedness and can inform optimally targeted measures to limit the impact on individuals and society.

Study objective

Estimate key transmission parameters of SARS-CoV-2 in Europe from observing within household virus spread and seroconversion of household members, and to characterize the views and experiences of households regarding perceptions, practices regarding infection control, and impacts of imposed isolation measures.

: In the RECOVER-VERDI household (CORONAthuis) substudy on SARS-CoV-2 reinfections, the overall aim is to investigate risk factors, including existing SARS-CoV-2-specific antibody immunity, and health impact of reinfections, including the nature, severity and duration of symptoms, during the autumn, winter and spring seasons of 2022-2023. This will allow to identify

populations at increased risk for reinfections, estimate the impact on individual health and society of reinfections and inform targeted measures to mitigate this impact.

Study design

This is a prospective observational cohort study of households with a confirmed SARS-Cov-2 infection in one of the household members. Households are enrolled as soon as possible following identification of the index case and no later than 2 days after a positive SARS-CoV-2 test. At enrolment, a nose-throat swab (NTS) and in a subset saliva is collected from each household member irrespective of symptoms. Follow-up for disease symptoms starts immediately after enrolment and continues daily for at least 21 days. Symptom follow-up will be prolonged in case a new suspected or confirmed SARS-CoV-2 emerges in the household during follow-up. In this case, follow-up is continued until 21 days after the date of onset of symptoms, or date of positive SARS-CoV-2 test in the last detected household case. At enrolment and at 4-6 weeks post-enrolment, a capillary blood sample on filter paper (dry-blot-spot) will be collected from all household members for SARS-CoV-2 serology testing. In a subset of participants, a qualitative interview by phone will be conducted to explore participants perceptions, needs and behavioural practices with respect to the COVID-19 pandemic.
As of January 2022, a more intensive sampling scheme will be used to comprehensively capture household transmission early after introduction. This has been decided based on results thus far of the household study that nearly all transmission occurs in the first week after detection of the index. In addition, several studies have now confirmed the added value of saliva sampling in detecting PCR positive individuals. Therefore, three NTS and saliva sampling time-points are added in the first week after enrollment (day 2, 4 and 7) and on day 14. Stool samples will be no longer requested. This has no added value to the repeated NTS and saliva samples and has proven cumbersome for participants.

For the substudy on reinfections, participants consenting to take part in the sub-study will undergo four additional 3-monthly sampling timepoints from November 2022 (M0) to July 2023 (M9). Biological specimens, clinical data and psychosocial data will be collected prospectively. Biological specimens that are collected include self-collected capillary blood by the participant (M0, M3, M6 and M9). During the same period, participants who develop new symptoms suggestive of SARS-CoV-2 reinfection or have a SARS-CoV-2 infection independent of symptoms, are instructed to self-collect a nose and throat swab and send to the laboratory. Self-administered questionnaires will also be collected at the predefined time-points and in case of suspected reinfection. The study will be conducted completely remote.

Study burden and risks

We estimate the risks for the participants to be small. Participants are sent all materials for collecting blood, nose-throat and some stools and saliva. Collecting the body material can be a little painful for the fingerstick and the nose-throat a bit annoying, but not painful. The questionnaires have been kept short and the diaries are quick and easy to complete.

Contacts

Public
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL
Scientific
Universitair Medisch Centrum Utrecht

Heidelberglaan 100
Utrecht 3584 CX
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adolescents (12-15 years)
Adolescents (16-17 years)
Adults (18-64 years)
Children (2-11 years)
Elderly (65 years and older)
Babies and toddlers (28 days-23 months)
Newborns

Inclusion criteria

Households are eligible if all members of the household or their legal guardians consent to participation and 1) are willing to complete diaries and questionnaires for the duration of follow-up, 2) are willing to, and capable of self-sampling nose-throat swabs, saliva (if applicable) and capillary blood samples by finger. If parents/caretakers of young children are reluctant to take a blood sample from their child, this is no reason for exclusion.

For the substudy starting in November 2022 participants who have participated in the household study will be eligible for the substudy.

Exclusion criteria

Patients or household members who are unable to consent, or do not wish to provide informed consent.
Children, pregnant women and patients lacking capacity will be included. Those lacking capacity to consent for themselves will be identified and consent will be sought from an appropriate consultee.
Households who do not have daily access to a smartphone or tablet with internet connection, will be excluded, as follow-up of households requires the use of an interactive diary App.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	21-04-2020
Enrollment:	1500
Type:	Actual

Ethics review

Approved WMO Date:	06-04-2020
Application type:	First submission
Review commission:	METC NedMec
Approved WMO Date:	06-05-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	26-05-2020
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	25-01-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	30-12-2021
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	22-12-2022
Application type:	Amendment
Review commission:	METC NedMec
Approved WMO Date:	05-07-2023
Application type:	Amendment
Review commission:	METC NedMec

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	NL73581.041.20