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Viral respiratory infections in young adults who are sharing housing with other young adults during the peak 2021/2022 common cold season in the Netherlands

Submission date
04/04/2022

Recruitment status
No longer recruiting

Registration date
26/04/2022

Overall study status
Completed

Last Edited
15/04/2025

Condition category
Infections and Infestations

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[X] Record updated in last year

Plain English Summary
Background and study aims
Influenza viruses, coronaviruses (such as SARS-CoV-2) and other common cold viruses cause infections in the respiratory tract and are therefore referred to as respiratory viruses. People can develop symptoms after contact with these viruses that can range from mild colds to serious complaints (such as shortness of breath and high fever). Sometimes people have no symptoms at all. Different respiratory viruses often cause the same type of symptoms, making it difficult to identify the pathogen based on symptoms alone.
To gain a better understanding of viral infections, people who live together in a shared household will be investigated on how often an infection with a certain respiratory virus occurs and how the respiratory viruses spread within households. In particular, interest lies in large households (eg student houses), because the infection could occur more often in these groups than in other, smaller households. The information from this research will be used for the development of new medicines against respiratory viruses. In the current study, no new drugs are being investigated.

Who can participate?
For this study 104 participants: women and men between the ages of 18 and 40 in shared households can be included. It is necessary that at least 2 adults from the same household participate in the survey. The household must consist of at least 4 adults. A household is defined as a group of (at least 4) adults who live together 'under one roof' and share facilities with each other. To participate in this study, a person must register together with one or more housemates. Not all household members need to be participants. Household members who agree to participate in the study must sign individual written informed consent forms. Household members who do not participate in the prospective observational study can choose to participate for the time they or another housemate are symptomatic with a respiratory infection after signing a separate written informed consent form.

What does the study involve?
Participants will be followed for 12 weeks during the peak 2021/22 common cold season in the Netherlands. To assess asymptomatic carriage, throat and nose swabs will be collected every 2 weeks and analysed. Serum and saliva samples will be collected at baseline to describe population serology, and at week 6 and week 12 to study seroconversion against respiratory viruses including corona- and influenza viruses. When participants present with ILI or acute respiratory illness, additional swabs and blood samples will be taken from the symptomatic participant and the other study participant(s) in the same household. This enables assessment of the incidence and aetiology of viral respiratory infections as well as potentially identification of transmission events that occur in this setting.
The whole conduct of the study will approximately take 3-5 months.

What are the possible benefits and risks of participating?
As no (medical) intervention will be used in this study, the burden for the volunteer is limited and only related to the study procedures. Only well-established methods of sample collection will be applied, with a known and limited risk and no or mild discomfort for the volunteer. No benefit for the subjects is expected from participation in the study.

Where is the study run from?
The research is being conducted by the Center for Human Drug Research (CHDR) in Leiden under the responsibility of Dr. Ingrid de Visser-Kamerling and is being conducted on behalf of Leyden Laboratories B.V. in Amsterdam.

When is the study starting and how long is it expected to run for?
May 2021 to June 2022

Who is funding the study?
Leyden Labs BV (Netherlands)

Who is the main contact?
Dr Lisanne Smidt, lsmidt@chdr.nl

Study website
https://proefpersoon.nl/actuele-chdr-onderzoeken

Contact information

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Public

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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
CHDR2053/LL10001

Study information

Scientific Title
Observational study to investigate incidence and aetiology of viral respiratory infections in young adults who are sharing housing with other young adults during the peak 2021/2022 common cold season in the Netherlands

Study hypothesis
This study aims to assess the incidence and aetiology of both symptomatic and asymptomatic viral respiratory infections in adults who live in shared housing during the peak of the 2021/22 common cold season in the Netherlands.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved, 12/11/2021, Medisch-Ethische Toetsingscommissie Leiden Den Haag Delft (Albinusdreef 2, 2300RC Leiden, Netherlands; +31 (071) 526 3241; metc-ldd@lumc.nl), ref: P21.093

Study design
Single centre observational study

Primary study design
Observational

Secondary study design
Epidemiological study

Study setting(s)
Other

Study type(s)
Other

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

Condition
Viral respiratory infections in adults.

Interventions
Participants will be followed for 12 weeks during the peak 2021/22 common cold season in the Netherlands. To assess asymptomatic carriage, throat and nose swabs will be collected every 2 weeks and analysed. Serum and saliva samples will be collected at baseline to describe population serology and at week 6 and week 12.

Intervention Type
Other

Primary outcome measure
1. The proportion of study participants developing symptomatic or asymptomatic virus-specific respiratory infections during the peak common cold season in the Netherlands as assessed by clinical symptoms, laboratory-based multiplex PCR testing (ePlex), and/or seroconversion:
1.1. Clinical symptoms assessed using the FluPRO Plus® questionnaire every time a subject experiences symptoms compatible with a respiratory infection.

1.2. Oro- and nasopharyngeal swabs for PCR testing collected every 2 weeks throughout the study period of 12 weeks, as well as, when a subject experiences symptoms compatible with a respiratory infection, or when a housemate has a symptomatic infection caused by any influenza or coronavirus.
1.3. Sera collected at screening (baseline), day 1, day 43 and day 85 will be assessed in the MesoScale Discovery (MSD) platform to evaluate seroconversion against respiratory viruses of interest during the 2021/22 winter season in the Netherlands
2. Virus-specific loads in the upper respiratory tract of asymptomatic and symptomatic participants:
2.1. Material from nasal and throat swabs will be used to quantify viral load by qPCR in samples that tested positive in ePlex

Secondary outcome measures
At baseline (screening) and during scheduled visits outside a symptomatic episode (day 1 and every 2 weeks until day 85), the concentration and seroprevalence of: serum IgG against influenza viruses, coronaviruses, and RSV; saliva IgA against influenza and coronaviruses

Overall study start date
02/05/2021

Overall study end date
30/06/2022

Eligibility

Participant inclusion criteria
1. Male or female, 18-40 years of age (inclusive) at screening;
2. Living in a shared household that include at least 4 adults within the age range of 18-40 years old, of whom at least 2 will be participating in the study
3. Sharing common spaces in the house, such as kitchen, living room, bathroom, etc. with household members mentioned above
4. Agreeing to sign the study informed consent form prior to any study-related procedure indicating that he or she understands the purpose, procedures and potential risks, and is willing to participate in the study;
5. Willing and able to complete the study procedures;
6. Has a primary care physician at the time of enrolment.

Participant type(s)
Healthy volunteer

Age group
Adult

Lower age limit
18 Years

Upper age limit
40 Years

Sex

Both

Target number of participants
104

Total final enrolment
104

Participant exclusion criteria
1. Received or plans to receive the 2021/22 seasonal flu vaccine during the study period;
2. Received COVID-19 vaccines 14 days or less before screening or during the study;
3. Is not protected against SARS-CoV-2 infection during the whole study period. In line with the National Institute for Public Health and Environment (RIVM in Dutch) guidance, a person is considered to be protected against COVID-19 if one or more of the following applies:
* it is more than 14 days since having received a second COVID-19 vaccination with the AstraZeneca, Pfizer or Moderna vaccine;
* it is more than 28 days since having received one COVID-19 vaccination with the Janssen vaccine;
* it is more than 14 days since having received one vaccination with any of the COVID19 vaccines used in the Netherlands, in combination with having had a previous (PCR proven) COVID-19 infection;
* a (PCR proven) COVID-19 infection within the past 6 months provided the end of these 6 months is after the ending of the study.
4. Plans to move homes during the study;
5. History of chronic rhinitis or (expected) active allergic rhinitis during the envisioned study period;
6. Women in the third trimester of pregnancy during the study period (Jan-May 2022);
7. Immunocompromised or having received clinically significant immunosuppressive medication or other immunomodulating agents (including investigational drugs) in the 3 weeks prior to the first study day and during the study or 5 half-lives of the drug;
8. Clinically significant nasal abnormalities that might interfere with nasal sampling procedures;
9. Loss or donation of blood over 500 mL within three months (males) or four months (females) prior to screening, or donation of plasma within 14 days of screening or intention to donate blood or blood products during the study;
10. Any known factor, condition, or disease that might interfere with compliance, study conduct or interpretation of the results, as deemed by the investigator.

Recruitment start date
22/11/2021

Recruitment end date
04/02/2022

Locations

Countries of recruitment
Netherlands

Study participating centre

Centre for Human Drug Research
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Sponsor information

Organisation
Leyden Laboratories B.V.

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Sponsor type
Industry

Website
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Funder(s)

Funder type
Industry

Funder Name
Leyden Laboratories B.V.

Results and Publications

Publication and dissemination plan
Internal report (CSR)
Publications in peer reviewed scientific journal(s)
Conference presentation(s)

Intention to publish date
01/12/2024

Individual participant data (IPD) sharing plan

Copies of the final de-identified dataset will be held by the investigator and sponsor. Reasonable requests for de-identified data can be made to the sponsor after publication of the study results.

IPD sharing plan summary

Available on request