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 2021/22 common cold season in the Netherlands.

Published: 12-11-2021
Last updated: 17-01-2025

Primary• To describe the incidence, aetiology and viral loads of (a)symptomatic viral respiratory infections in adults (18-40 years) who live in shared housing with at least 3 other adults during the peak common cold season in the...

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

Summary

ID

NL-OMON52306

Source
ToetsingOnline

Brief title
Viral respiratory infections in adults

Condition

- Viral infectious disorders

Synonym
common cold, Viral respiratory infections

Research involving

Human

Sponsors and support

Primary sponsor: Leyden Labs BV
Source(s) of monetary or material Support: Leyden Labs BV

Intervention

Keyword: Aetiology, Common cold, Incidence, Viral respiratory infections

Outcome measures

Primary outcome

• The proportion of study participants developing symptomatic or asymptomatic virus specific respiratory infections as assessed by clinical symptoms, laboratory-based multiplex PCR testing (ePlex), and/or seroconversion

• Virus-specific loads in the upper respiratory tract of asymptomatic and symptomatic participants

Secondary outcome

• Overall risk of infection for each respiratory virus defined as the proportion of susceptible adult household contacts of an index case who subsequently become infected.

• The risk of infecting (transmission) an adult household contact relative to viral load for each respiratory virus

• At baseline and during scheduled visits outside a symptomatic episode, the concentration and seroprevalence of: hemagglutination inhibition (HI) titres against influenza viruses, serum IgG against coronaviruses; saliva IgA against influenza and coronaviruses

Study description

Background summary

Respiratory viruses are a major cause of upper and lower respiratory tract infections during the winter season in temperate regions. Severity of viral respiratory illness varies widely, from asymptomatic to hospitalization and death especially in high-risk groups, which poses a global health burden. Most respiratory viruses, including, but not limited to, influenza, parainfluenza, rhinovirus, coronavirus and respiratory syncytial virus (RSV), present with common viral respiratory syndromes, such as common cold. This makes it challenging to identify the causative agent of the disease based on symptoms alone.

Study objective

Primary
• To describe the incidence, aetiology and viral loads of (a)symptomatic viral respiratory infections in adults (18-40 years) who live in shared housing with at least 3 other adults during the peak common cold season in the Netherlands

Secundary
• To evaluate transmission of respiratory viruses between adults within households.
• To describe systemic and mucosal antibody responses against respiratory viruses at a population level in healthy adults.

Study design

This is a descriptive observational study that is part of the clinical development trajectory of intranasal prophylaxes and/or therapeutics against respiratory viruses. A total of 104 adults (aged 18-40 years) living in shared housing (minimum of 4 adults in 1 household) will be enrolled. The study will consist of a screening visit and 7 follow-up visits at the Clinical Research Unit (CRU) divided over a period of 12 weeks. Additional visits will be scheduled if a participant or an individual in a participant*s household becomes symptomatic and/or tests positive for a respiratory virus along the course of the study. During the study, nasal and throat swabs will be collected every 2 weeks and saliva and blood will be collected on the first visit, week 6 and week 12 for the study endpoints to identify seroconversion against respiratory viruses during the season. Screening for eligibility will be conducted at CHDR and blood samples will be collected at this time. Participants will be asked to contact CHDR if there are changes at the time of enrolment and at the end of the study from asymptomatic infected adults and non-infected participating household members, as well as from symptomatic

infected adults including samples collected 2 weeks after onset of ARI/ILI in their health status. Participants from 1 household should ideally start at the same moment or within a period of one week of start of the first housemate. When a study participant, or any other member of a household where study participants live, shows signs of respiratory infection and/or tests positive for a respiratory virus, the members of the household who are not part of the study will be asked whether they are willing to participate in sample collection for contact tracing of the primary case in that household only. Additional visits for symptomatic cases with a corona- or an influenza virus and their contacts will be scheduled at the time points when the probability of virological confirmation of an infection from swabs is highest. An additional informed consent form will be prepared for these situations. This will provide the opportunity to analyze transmission of respiratory viruses more accurately.

Study burden and risks

This study does not involve any investigational drugs. The benefit obtained is acquiring the knowledge on incidence and transmission events of respiratory viruses in this adult population in order to evaluate the feasibility of conducting clinical trials with prophylactic compounds in development in this study population and inform the design of such trials. 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. In addition, all collections will be performed according to standard operating procedures, by qualified medical staff.

Contacts

Public
Leyden Labs BV

Keizersgracht 290 A
Amsterdam 1016 EW
NL
Scientific
Leyden Labs BV

Keizersgracht 290 A
Amsterdam 1016 EW
NL

Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

Inclusion criteria (applicable to all participants in the study, including housemates who only participate in contact visits)
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.

Exclusion criteria

Exclusion criteria (applicable to participants who will take part in the whole study, but not to those who only take part in contact visits)
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 (COVID-19 vaccine boosters during the study are allowed);
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 COVID-19 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 and not including vaccines except for the 2021/22 seasonal influenza vaccine) 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.

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Completed
Start date (anticipated):	12-11-2021
Enrollment:	104
Type:	Actual

Ethics review

Approved WMO Date:	12-11-2021
Application type:	First submission
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	24-11-2021
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

Approved WMO Date:	07-03-2022
Application type:	Amendment
Review commission:	METC Leiden-Den Haag-Delft (Leiden) metc-ldd@lumc.nl

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	NL76302.058.21

Study results

Date completed: 06-05-2022

Results posted: 12-06-2023

First publication
28-05-2023