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Respiratory virus background immunity assessment

Submission date	Recruitment status	[_] Prospectively registered
19/02/2024	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
21/02/2024	Ongoing	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
24/02/2024	Infections and Infestations	[_] Record updated in last year

Plain English summary of protocol

Background and study aims
Viruses such as influenza, rhinovirus and SARS-CoV-2 cause respiratory tract infections throughout the general population, affecting elderly and infants most severely. Annual deaths caused by respiratory viruses are estimated to be up to 3 million, and medical costs and loss of productivity amount to a considerable impact on global economy. In temperate regions, incidence of e.g. influenza is highly seasonal, with outbreaks generally beginning after November, and peaks subsiding before April. Vaccination is the most cost-effective strategy to globally reduce incidence and mortality of respiratory viruses, though several challenges remain. Major problems include the necessity to frequently develop a new vaccine for highly mutagenic viruses such as influenza, or the limited understanding of the pathogenicity for viruses such as RSV or SARS-CoV-2. Continuous assessment and mapping of mutating respiratory viruses is a cornerstone of vaccine development.
CHDR collaborates with multiple parties involved in the development of vaccines and therapeutic agents for respiratory viruses. A major contribution to this development will be the conducting of controlled human infection models (CHIMs) to evaluate clinical safety and efficacy of vaccines and antivirals. To select virus stems apt for this model, assessment of circulating respiratory viruses in The Netherlands is essential; a high immunity in the general population against the challenge virus would significantly limit the value of a CHIM, while a low general immunity would increase the risks of major viral outbreaks. Since for every CHIM individually this consideration is to be made, it is essential to assess the existing immunity in our population on a regular basis. This way, this protocol serves as a preparatory study to future vaccine research at CHDR.

Who can participate?
Healthy volunteers in the age range of 18 - 75 years

What does the study involve?
In this trial, serum samples from healthy volunteers will be collected for analysis. Serum will be collected from subjects that are already planned to visit CHDR for another study to undergo medical screening or follow-up. These healthy volunteers will be asked permission to collect

serum, in addition to the blood already collected for screening or follow-up purposes. This way, no extra activity is required from subjects and total blood sampling will not exceed the total amount of 500 mL blood.

What are the possible benefits and risks of participating?
No investigational drug will be administered to the volunteers in this study. The invasive procedures under this protocol will be restricted to blood sample collection (venipuncture). The burden for the volunteer related to the study procedures is limited. 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 by qualified medical staff.

Where is the study run from?
The Centre for Human Drug Research (Netherlands)

When is the study starting and how long is it expected to run for?
September 2023 to October 2030

Who is funding the study?
The Centre for Human Drug Research (Netherlands)

Who is the main contact?
Mr Victor Cnossen, clintrials@chdr.nl

Contact information

Type(s)
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Additional identifiers

Protocol serial number
CHDR2348

Study information

Scientific Title
Seasonal assessment of existing immunity for respiratory viruses in healthy volunteers to facilitate targeted vaccine development – a preparatory study

Study objectives
Viruses such as influenza viruses, rhinovirus and SARS-CoV-2 cause respiratory tract infections throughout the general population, affecting elderly people and infants most severely. Annual deaths caused by respiratory viruses are estimated to be up to 3 million, and medical costs and loss of productivity amount to a considerable impact on global economy. In temperate regions, incidence of e.g. Influenza is highly seasonal, with outbreaks generally beginning after November, and peaks
subsiding before April.
Vaccination is the most cost-effective strategy to globally reduce incidence and mortality of respiratory viruses, though several challenges remain. Major problems include the necessity to frequently develop a new vaccine for highly mutagenic viruses such as influenza viruses, or the limited understanding of the pathogenicity for viruses such as RSV or SARS-CoV-2. Continuous assessment and mapping of mutating respiratory viruses is a cornerstone of vaccine development.

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 22/09/2023, Medische Ethische Toetsingscommissie Leiden Den Haag Delft (Postal zone P5-P, Leiden, 2300 RC, Netherlands; +31 71 52 63241; metc-ldd@lumc.nl), ref: 029

Study design
Observational exploratory

Primary study design
Observational

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Viral infection, respiratory tract infections

Interventions
In this trial, serum samples from healthy volunteers will be collected for analysis. Serum will be collected from subjects that are already planned to visit CHDR for screening or follow-up for a different study. These healthy volunteers will be asked permission to collect serum, in addition to the blood already collected for screening or follow-up purposes. This way, no extra activity is required from subjects.
Recruitment of participants is not done separately; when the planned screening or follow-up date for the other trial they participate in falls within the study period of this trial, subjects will be asked consent for the additional blood donation. Participants will be given time to consider participation for as long as is necessary. Our aim is to be able to execute this protocol when necessary; for example, when a scientific question emerges regarding existing immunity, or for the selection of a virus strain for a controlled human infection model. This protocol may be executed multiple times per year, with a maximum of 500 subjects per year.

Intervention Type
Other

Primary outcome(s)
Assess existing background immunity for respiratory virus stems in the general population using laboratory assessments containing,
but not limited to:
1. Hemagglutination inhibiton assay (HAI) titre for selected viral stems, for influenza
2. Microneutralization assay (MN) titre for selected viral stems
3. (Neutralizing) IgG & IgA titre for selected viral stems
Serum will be collected from subjects that are already planned to visit CHDR for screening or follow-up for a different study.

Key secondary outcome(s))
There are no secondary outcome measures

Completion date
27/10/2030

Eligibility

Key inclusion criteria
1. Aged 18-75 years and in good health; the upper age limit could be lowered for different executions of this protocol, but will never exceed 75 years
2. Good health, based upon the results of medical history
3. Subject has signed informed consent

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
75 years

Sex
All

Key exclusion criteria
1. Evidence of immunodeficiency in medical history
2. Prior use of immunosuppressive medication (systemic glucocorticoids 6 months prior to inclusion or any other systemic immunosuppressive medication at any time), immunoglobulins or systemic antiviral therapy)

Date of first enrolment
23/09/2023

Date of final enrolment
01/06/2025

Locations

Countries of recruitment
Netherlands

Study participating centre
The Centre for Human Drug Research
Zernikedreef 8
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Sponsor information

Organisation
Centre for Human Drug Research

ROR
https://ror.org/044hshx49

Funder(s)

Funder type
Other

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan
The data-sharing plan for the current study are unknown and will be made available at later date.

IPD sharing plan summary
Available on request