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

Published: 22-09-2023
Last updated: 26-10-2024

To assess existing background immunity for respiratory virus stems in the general population.

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Respiratory tract infections
Study type	Observational invasive

Summary

ID

NL-OMON56235

Source
ToetsingOnline

Brief title
Respiratory virus background immunity assessment

Condition

- Respiratory tract infections

Synonym
respiratory tract infections, viral infection

Research involving
Human

Sponsors and support

Primary sponsor: Centre for Human Drug Research
Source(s) of monetary or material Support: Centre for Human Drug Research

Intervention

Keyword: Respiratory tract infections, Vaccine development

Outcome measures

Primary outcome

To assess existing background immunity for respiratory virus stems in the

general population using laboratory assessments containing, but not limited to:

• Hemagglutination inhibiton assay (HAI) titre for selected viral stems, for

Influenza

• Microneutralization assay (MN) titre for selected viral stems

• (Neutralizing) IgG & IgA titre for selected viral stems

Secondary outcome

Not applicable.

Study description

Background summary

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.

Study objective

To assess existing background immunity for respiratory virus stems in the general population.

Study design

This protocol describes a cross-sectional investigation of existing immunity for respiratory virus stems. The blood specimens required for this research will originate from volunteers recruited for participation of other clinical trials at CHDR. The total duration of the study for each subject will be a single visit, being the screening visit for the clinical trial. Screening visits regularly last no longer than 2 hours. During the visit, subject*s eligibility for this study will be assessed prior to blood sample collection.

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 including 500 subjects per year; when executed, we intend to collect blood samples within a short period of time, e.g. 2 weeks, to relieve operational departments of structural burdens and to minimize the effects of possible new viruses on the data.

Study burden and risks

No investigational drug will be administered to the volunteers. 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.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)

Inclusion criteria

1. Age 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.

Exclusion criteria

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

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	16-10-2023
Enrollment:	3500
Type:	Actual

Ethics review

Approved WMO

Date:	22-09-2023
Application type:	First submission
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	NL85006.058.23