Surveillance of rEspiratory viruses iN healThcare and animal workers in the NethErLands

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The primary objective of the study is to determine the incidence and aetiology of symptomatic and asymptomatic respiratory virus infections in hospital workers (HCW) and animal workers (AW). The secondary objective is to evaluate immune responses...

Ethical review Approved WMO

Status Pending

Health condition type Viral infectious disorders **Study type** Observational invasive

Summary

ID

NL-OMON56919

Source

ToetsingOnline

Brief titleSENTINEL

Condition

Viral infectious disorders

Synonym

airway infection, respiratory infection

Research involving

Human

Sponsors and support

Primary sponsor: Erasmus MC, Universitair Medisch Centrum Rotterdam

Source(s) of monetary or material Support: ZonMW

Intervention

Keyword: Immunity, Respiratory viruses, Surveillance

Outcome measures

Primary outcome

The main study endpoint is the early detection of respiratory virus infections that occur in HCW or AW, and the identification of the causative agent during the observation period.

Secondary outcome

Secondary study endpoints include the assessment of local and systemic virus-specific immune responses, risk factors, data on infection kinetics, and genetic variation between causative viruses after a respiratory tract infection or vaccination against respiratory viruses.

Study description

Background summary

Outbreaks with viruses occur continuously, and novel viruses or new variants of existing viruses can surface after a zoonotic event or human-to-human transmission. This project proposal is designed to detect early circulation of (novel) respiratory viruses in both symptomatic and asymptomatic participants, either by direct detection of the virus or changes in local or systemic immunity. Additionally, SENTINEL will provide information on infectivity and (protective) immune responses in viral outbreaks or vaccination campaigns.

Study objective

The primary objective of the study is to determine the incidence and aetiology of symptomatic and asymptomatic respiratory virus infections in hospital workers (HCW) and animal workers (AW). The secondary objective is to evaluate immune responses against respiratory viruses and vaccines.

Study design

Prospective follow-up study of HCW and AW to establish a biobank in which incidence, infection kinetics and virus-specific immune responses can be investigated.

Study burden and risks

In this protocol, nose samples and venepunctures will be obtained from participants at multiple timepoints over a maximum period of 5 years. The procedures will either take place in the hospital or via home sampling. The risk of the proposed procedures is negligible. Participants have no direct benefit from this study other than that they will be notified when validated PCR tests detect recent virus infections to allow them to take personal measures to prevent spread accordingly.

Contacts

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Scientific

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age

Adults (18-64 years) Elderly (65 years and older)

Inclusion criteria

18 years old and above

Exclusion criteria

none

Study design

Design

Study type: Observational invasive

Masking: Open (masking not used)

Control: Uncontrolled

Primary purpose: Diagnostic

Recruitment

NL

Recruitment status: Pending

Start date (anticipated): 01-07-2024

Enrollment: 0

Type: Anticipated

Ethics review

Approved WMO

Date: 30-07-2024

Application type: First submission

Review commission: METC Erasmus MC, Universitair Medisch Centrum Rotterdam

(Rotterdam)

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 NL86800.078.24