Prevalence, burden, and shedding patterns of respiratory viral infections on the ICU

No registrations found.

Ethical review	Positive opinion
Status	Recruitment stopped
Health condition type	-
Study type	Observational non invasive

Summary

ID

NL-OMON24850

Source
NTR

Brief title
COURSE

Health condition

respiratory viruses, critically ill patients, ICU, viral infection, viral burden, viral shedding, respiratoire virussen, kritisch zieke patiënten

Sponsors and support

Primary sponsor: Academic Medical Center (AMC), Amsterdam, the Netherlands
Source(s) of monetary or material Support: Academic Medical Center (AMC), Amsterdam, the Netherlands; Crucell Holland B.V., the Netherlands

Intervention

Outcome measures

Primary outcome

The prevalence of viral respiratory infections in newly and acutely admitted, intubated ICU

patients

Secondary outcome

1) Burden of viral respiratory infections

2) Qualitative and quantitative viral shedding patterns in upper and lower respiratory tract of virus positive ICU patients

3) Correlation between viral shedding patterns with clinical manifestations and outcome

4) Correlation between viral and bacterial co-infections with clinical manifestations and outcome

Study description

Background summary

Introduction:

There is uncertainty on the epidemiology of viral respiratory infections amongst critically ill patients. Furthermore, there is no established predictive relationship between extent of clinical signs and symptoms and patterns of viral shedding.

Study design:

This is a national multi-centre prospective observational study to investigate the epidemiology and viral shedding patterns of viral respiratory infections in ICU-patients.

Patients:

Consecutive critically ill patients aged 18 year-old or older who are newly and acutely admitted to an ICU of participating hospitals will be included in this study. Clinical data will be collected for all patients to determine several outcome parameters. Samples will be collected daily until successful weaning from mechanical ventilation to determine viral shedding in these patients.

Objectives:

The primary objective of the study is to assess the prevalence and burden of viral infection in critically ill patients. The secondary objective is to assess the viral shedding pattern in virus-positive ICU-patients and the correlation with the clinical manifestation and outcomes.

Main study parameters/endpoints:

Prevalence of viral infection, overall and by virus types in critically ill intubated patients. For all patients: daily severity scores; clinical outcomes, including ICU- and hospital mortality, 15-, 28-, 90- and 180-day mortality, mechanical ventilation-free days at day 28; length of stay in ICU and hospital; for patients with confirmed viral respiratory infection: viral shedding (qualitative and quantitative viral measures at ICU admission, days to viral clearance, quantitative measures).

Statistical considerations:

This is an observational study to assess prevalence, burden and shedding patterns of respiratory viruses; hence there is no target sample size. During 8 months we will include patients meeting the inclusion criteria in 6 ICU's in the Netherlands (AMC, Erasmus Hospital, Gelre Hospital, LUMC, UMC Utrecht, VUMC). Patient characteristics between patients with and patients without an viral infection will be compared and described by appropriate statistics; continuous variables by descriptive statistics (number of patients [n], mean, standard deviation, minimum, median, maximum), categorical data by absolute and relative frequencies (n and %) or contingency tables. Mean changes in viral measures over time will be calculated using analysis of repeated measures in order to gain knowledge on the variation of relevant parameters. The rate of freedom from mechanical ventilation as well as mortality will be analyzed according to the Kaplan-Meier method and the results will be compared with the log-rank test.

Nature and extent of the burden and risks associated with participation, benefit and group relatedness:

Pharyngeal swabs and tracheal aspirates are routinely performed several times per day to remove mucous from the airways from intubated and adequately sedated patients (to avoid obstruction of the tube). These pharyngeal swabs and tracheal aspirates are considered waste material. These procedures will not have an additional burden for the patients. Pharyngeal swabs and tracheal aspirates will be collected only from intubated patients. Informed consent waiver received from the Ethics Committee of the Academic Medical Center in Amsterdam, the Netherlands.

Study objective

We hypothesize that respiratory viruses are frequently unrecognized as the causative pathogen of respiratory failure in critically ill patients. The aim of this study is to asses the prevalence and burden of respiratory viral infections in acutely admitted ICU patients.

Study design

- at admission: demographic data, clinical data, pharyngeal swab, tracheal aspirate

- daily, until extubated or successfully weaned: clinical data, pharyngeal swab, tracheal aspirate

- at day 15, 28, 90, 180: ICU and hospital discharge status, mortality

Intervention

N/A

Contacts

Public
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Scientific
F. Someren Greve, van
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The Netherlands

Eligibility criteria

Inclusion criteria

1) 18 years or older

2) newly and acutely admitted to ICU

3) intubated

Exclusion criteria

elective ICU admission (e.g. planned admission after scheduled surgery)

Study design

Design

Study type:	Observational non invasive
Intervention model:	Other
Masking:	Open (masking not used)
Control:	N/A , unknown

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	01-09-2013
Enrollment:	0
Type:	Actual

Ethics review

Positive opinion

Date:	20-08-2013
Application type:	First submission

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
NTR-new	NL2578
NTR-old	NTR4102
Other	Ethics Committee of the Academic Medical Center in Amsterdam : W12_262
ISRCTN	ISRCTN wordt niet meer aangevraagd.

Study results

Summary results
N/A