Influenza-associated pulmonary aspergillosis (IAPA) in ICU patients with severe influenza: incidence and host- and pathogen related risk factors

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A prospective multi-center observational study to assess the incidence of influenza-associated pulmonary aspergillosis (IAPA) in ICU patients and to identify host- and pathogen related risk factors for IAPA in EORTC negative ICU patients with severe...

Ethical review	Approved WMO
Status	Recruiting
Health condition type	Fungal infectious disorders
Study type	Observational invasive

Summary

ID

NL-OMON55031

Source
ToetsingOnline

Brief title
Prospective observational trial of IAPA

Condition

- Fungal infectious disorders

Synonym
Influenza-associated pulmonary aspergillosis, pulmonary fungal infection

Research involving
Human

Sponsors and support

Primary sponsor: Radboud Universitair Medisch Centrum

Source(s) of monetary or material Support: Horizon 2020

Intervention

Keyword: Influenza-associated pulmonary aspergillosis, Intensive care, Severe influenza

Outcome measures

Primary outcome

The incidence of IAPA-infection at ICU discharge

Secondary outcome

Time to IAPA diagnosis, length of stay at ICU/hospital and mortality

Study description

Background summary

Invasive pulmonary aspergillosis was shown to be a complication of severe influenza infections in immunocompromised patients as well as in immunocompetent patients and is associated with a high mortality. Antifungal prophylaxis might prevent influenza-associated pulmonary aspergillosis (IAPA) and thus might improve the outcome in patients with severe influenza. However, clinical related risk factors should be identified to assess whether a patient will benefit from antifungal prophylaxis.

Study objective

A prospective multi-center observational study to assess the incidence of influenza-associated pulmonary aspergillosis (IAPA) in ICU patients and to identify host- and pathogen related risk factors for IAPA in EORTC negative ICU patients with severe influenza.

Study design

Prospective multi-center observational study.

Study burden and risks

The nature and extent of the burden and risks associated with participation are considered negligible, as the proposed study does not apply an intervention to the patients. The only burden will be collection of samples which are

procedures of minimal additional risk.

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

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

Inclusion criteria

Patients with a PCR-positive respiratory virus panel (RVP) result for influenza within 96 hours before or 48 hours after ICU admission.
Patients who require ICU admission for more than 24 hours for severe influenza.
Patients who have respiratory distress (respiratory rate >= 25x/minute and paO2/fiO2 < 300 with or without bilateral infiltrates) as the main reason for ICU admission.
Patients who do not have an EORTC host factor.
Patients who are at least 18 years of age.

Exclusion criteria

Patients with age < 18 years as extensive sampling is required
Expected survival on ICU admission <= 48h
Patients that are being treated actively with antifungal agents for invasive aspergillosis.
Patients or their legal representatives who did not sign the informed consent form.

Study design

Design

Study type:	Observational invasive
Intervention model:	Other
Allocation:	Non-randomized controlled trial
Masking:	Open (masking not used)
Control:	Active
Primary purpose:	Basic science

Recruitment

NL

Recruitment status:	Recruiting
Start date (anticipated):	10-03-2022
Enrollment:	90
Type:	Actual

Ethics review

Approved WMO Date:	16-08-2021
Application type:	First submission
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)
Approved WMO Date:	10-01-2022

Application type:	Amendment
Review commission:	CMO regio Arnhem-Nijmegen (Nijmegen)

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
ClinicalTrials.gov	NCT04530799
CCMO	NL74862.091.20