Microbiological etiology of community acquired pneumonia in immunocompromised adults.

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Ethical review	Approved WMO
Status	Recruitment stopped
Health condition type	Bacterial infectious disorders
Study type	Observational non invasive

Summary

ID

NL-OMON44107

Source
ToetsingOnline

Brief title
CAP-Extra

Condition

- Bacterial infectious disorders
- Respiratory tract infections

Synonym
Lower Respiratory Tract Infection, Pneumonia

Research involving
Human

Sponsors and support

Primary sponsor: Universitair Medisch Centrum Utrecht
Source(s) of monetary or material Support: Wyeth,Wyeth Nederland

Intervention

Keyword: Community Acquired Pneumonia, Etiology, Immunocompromised

Outcome measures

Primary outcome

To quantify the microbiological etiology in immunocompromised patients, at least 18 years of age, with CAP needing hospitalization.

Secondary outcome

To determine the severity, antibiotic use and outcome of CAP in immunocompromised patients, at least 18 years of age, with CAP needing hospitalization.

Study description

Background summary

In a previous observational study 23% of Community Acquired Pneumonia (CAP) episodes among adults in the Netherlands were caused by pneumococci with serotypes that are included in the 13-valent conjugate pneumococcal vaccine (13v PnV). In the CAPiTA trial 84.500 healthy elderly have been randomized to receive either 13v PnV or placebo, and the incidence of CAP needing hospitalization and caused by any of the 13 vaccine serotypes is the primary study endpoint. Yet, study participation was based on strict inclusion criteria, intentionally creating selection of healthy elderly. Moreover, the decision to participate among eligibles may also induce selection bias (*healthy vaccinee effect*). Therefore, the study population may not be considered generalizable for the whole population of elderly in the Netherlands, and it is unknown to what extent the microbiological etiology of the study population differs from other patient populations. This knowledge gap may influence acceptance of the CAPiTA study results.

Study objective

Objective of the study is to quantify the microbiological etiology in immunocompromised patients, at least 18 years of age, with CAP needing hospitalization. And to determine the severity, antibiotic use and outcome of

CAP in immunocompromised patients, at least 18 years of age, with CAP needing hospitalization.
Urine for the SSUAD test will be collected from immune-compromised patients with NO suspicion of a respiratory infectious disease or other acute infectious disease.

Study design

This is an observational study. Patient will be included based on the suspicion fo CAP. The final diagnosis of CAP will be based on the presence of enough clinical criteria and presence of an infiltrate on the chest X-ray. When there is no more suspicion of CAP within 48 hours after admission, patient will not be included. The final interpretation of the chest X-ray wil be done by independent radiologists.
The microbiological etiology will be determined upon clinical cultures (blood, sputum and pleural fluid if indicated), urinary antigen testing (BINAX for pneumococci and Legionella when clinically indicated), virological examination of throat swab and the SSUAD test for serotype specific pneumococcal antigen identification. These diagnostic procedures are identical to the ones used for CAPiTA patients, with the exception of collection of blood sample.
On presentation on the ER or within 24 hours after admission two study samples will be taken: 1 pharyngeal swab and 1 urine sample, at least 5mL. Within 48 hours after admission the patient will be asked permission to use these samples for diagnostic research. If no permission is obtained, the samples will be destroyed. If the patient does give permission for participation in the trial and thereby confirming use of the pharyngeal swab and urine sample, these samples will be analyzed in a central laboratory.
Urine for the SSUAD test will be collected from immune-compromised patients with NO suspicion of a respiratory infectious disease or other acute infectious disease.

Study burden and risks

Burden: 1 pharyngeal swab is taken.
Risks: itchy feeling in the throat, coughing, feeling of throwing up.

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

For the 1000 CAP patients:
Immunocompromised patients, aged 18 years or older with suspicion of CAP defined as the presence of at least two of the following symptoms: fever/ hypothermia, cough, sputum production, dyspnea/ tachypnea/ hypoxia, percussion/ auscultatory findings consistent with pneumonia, leucocytosis/ leukopenia/ left shift or new infiltrate on chest X-ray. ;For the 400 controls:
Adults (18 years or older) with an immune-compromising condition, and able to provide urine.

Exclusion criteria

For the 1000 CAP patients:
- Patients with recent hospitalization (<2 weeks)/ residing in long-term care facilities.
- CAPiTA participants.;For the 400 controls:
- Subjects with suspicion of CAP or other respiratory infectious diseases, as well as evidence of or documented concomitant infectious disease within 14 days of the day of inclusion.
- Subjects with fever (measured temperature of *38.0°C measured by a healthcare provider).
- Subjects residing in any long-term care facilities (for example, nursing homes, respite care facilities, etc.).
- Subjects with either pneumococcal conjugate vaccine (PCV) and/or pneumococcal polysaccharide vaccine (PPV) administration within the past 30 days.

Study design

Design

Study type: Observational non invasive

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

Recruitment

NL

Recruitment status:	Recruitment stopped
Start date (anticipated):	09-02-2011
Enrollment:	1400
Type:	Actual

Ethics review

Approved WMO

Date:	06-01-2011
Application type:	First submission
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO

Date:	01-04-2011
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO

Date:	12-04-2011
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO

Date:	07-02-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

Approved WMO

Date:	18-06-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	25-10-2012
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	05-09-2013
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	28-07-2015
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Not approved Date:	18-05-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)
Approved WMO Date:	07-12-2016
Application type:	Amendment
Review commission:	METC Universitair Medisch Centrum Utrecht (Utrecht)

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	NL32513.041.10