Study on the aetiology of Community Acquired Pneumoniae in patients visiting the emergency room of a Dutch hospital

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Improve the insight in the aetiology of CAP by season and by population in the Netherlands by the use of an extensive combination of microbiological techniques.Moreover this study will provide an unique sample from a well defined patient population...

Ethical review	-
Status	Pending
Health condition type	Hepatobiliary neoplasms malignant and unspecified
Study type	Observational invasive

Summary

ID

NL-OMON30890

Source
ToetsingOnline

Brief title
Study on the aetiology of CAP

Condition

- Hepatobiliary neoplasms malignant and unspecified
- Respiratory tract infections

Synonym
CAP pneumoniae

Research involving
Human

Sponsors and support

Primary sponsor: RIVM
Source(s) of monetary or material Support: Ministerie van OC&W

Intervention

Keyword: aetiology, CAP, hospital, pneumoniae

Outcome measures

Primary outcome

Aetiological agents of CAP will be identified using an extensive combination of microbiological techniques (including culture, PCR, serology and rapid antigen detection).

Secondary outcome

Other parameters include specific host factors like age and co morbidity and the severity of CAP. These will be studied in relation with the detected aetiological pathogens.

Study description

Background summary

Community Acquired Pneumonia (CAP) is defined as an acute symptomatic infection of the lower respiratory tract which develops outside the hospital or nursing home. CAP can be a life threatening disease especially in the elderly and in the presence of co morbidity. In recent years CAP has an incidence of 5-10 cases per 1000 persons a year in the Netherlands and is a major cause of morbidity, hospitalization and mortality. CAP can be caused by many different pathogens. However little is known about the exact aetiology of CAP in the Netherlands as this requires extensive microbiological testing which is only performed on a limited scale. Furthermore, studies already performed show strong variations in the incidences of different pathogens.

Study objective

Improve the insight in the aetiology of CAP by season and by population in the Netherlands by the use of an extensive combination of microbiological techniques.
Moreover this study will provide an unique sample from a well defined patient population, which can supply essential reference information when in the future

(new) pathogens will be identified as a potential cause of CAP. Secondary objectives include prospective validation of new diagnostic tests for certain pathogens as well as comparison of accepted biomarkers of infection with potentially new biomarkers.

Study design

Prospective observational study.

Study burden and risks

For all patients participating in the study, routine sampling will involve collection of sputum and blood to guide therapeutic decisions as usual. Furthermore, additional blood, serum, urine, nose swab and throat swab will be collected. Urine antigen tests for S. pneumoniae and L. pneumophila, both important CAP related pathogens, will be performed. These tests can be done easily and rapidly, but are not routinely used at JBZ yet. Because the test results will be available in a clinical relevant time period, this might positively influence treatment choices from a broad spectrum antibiotic treatment to a pathogen directed antibiotic treatment. The other additional microbiological investigations are not expected to have a direct benefit for the patient as the test results will not be available in a clinical relevant time. However, better understanding of the pathogenesis of CAP is of public health importance since it might influence future treatment.

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

Age >= 18 years
Visiting emergency room of JBZ with (suspicion) of CAP according to the guidelines of the Dutch Working Party on Antibiotic Policy (SWAB,2005)
Written informed consent

Exclusion criteria

Age < 18 years
Patients transferred from another hospital
Patients residing in a nursing home

Study design

Design

Study type: Observational invasive

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

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	01-09-2007
Enrollment:	600

Type:	Anticipated

Ethics review

Approved WMO Date:	05-11-2008
Application type:	Amendment
Review commission:	METC Brabant (Tilburg)

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	NL18156.028.07