

# 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...

<b>Ethical review</b>	-
<b>Status</b>	Pending
<b>Health condition type</b>	Hepatobiliary neoplasms malignant and unspecified
<b>Study type</b>	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**

### **Public**

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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

Age  $\geq 18$  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