# Prestudy Optimizing Diagnosis of Community-Acquired Pneumonia

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| **Ethical review** | Approved WMO |
| **Status** | Recruitment stopped |
| **Health condition type** | Helminthic disorders |
| **Study type** | Observational non invasive |

## Summary

### ID

NL-OMON31562

**Source**
ToetsingOnline

**Brief title**
CAP study

### Condition

- Helminthic disorders
- Respiratory disorders NEC

**Synonym**
lower respirory tract infection, pneumonia

**Research involving**
Human

### Sponsors and support

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

## Intervention

**Keyword:** diagnosis, elderly, pneumococcal vaccination, pneumonia

## Outcome measures

### Primary outcome

Optimalization of the diagnostic protocol in adults admitted with suspected pneumonia. Outcome is the adherence to the proposed protocol (which is internationally consider optimal). The aim is a compliance of >95%.

### Secondary outcome

Determination of specificity and additional diagnostic value of the new diagnostic tests in blood and urine. The outcome is specificity and the aim is 100%.

# Study description

### Background summary

The standard diagnostic protocol for patients with suspected lower respiratory tract infection (including pneumonia) includes medical history taking, physical examination, and laboratory and microbiological testing. It is widely accepted that antimicrobial therapy should be targetted to the causative microorganism. Nevertheless, sensitivity of current microbiological tests is low. In over 50% of cases, the causative micro-organism is not found
According tot the 'the Infectious Disease Society of America' (2007) guidelines, cultures of blood and sputum, and urine antigen testing for Legionella and S.Pneumonia should be performed in all patients admitted with suspected pneumonia. Also, analysis of blood samples (hematological and biochemical) and interpretation of a chest x-ray should be performed.
The proposed study evaluates the implementation of a standardized diagnostic protocol (including all of the above), with the addition of two new diagnostic tests (in blood and urine) for patients admitted with suspected pneumonia.

### Study objective

The objective of the standardized protocol is optimalizing the accuracy of the

diagnosis (all-cause pneumonia, or serotype-specific pneumonia) during the 13-valent pneumococcal vaccin (13vPnC) study which will be performed in 2008. Additionaly, the added diagnostic value of the two new techniques (blood and urine testing) for detection of S. Pneumonia will be studied.

### Study design

On admission, an extra vial (10 ml blood) will be taken during routine bloodsampling. An additional sample (25 ml urine) will be taken during routine urinesampling. Within 24-48 hours after admission, informed consent will be asked to use these materials for diagnostic research. If no consent is given, the materials will be destroyed.
When informed consent is given for participation in the study, the materials will be analysed in the central laboratory.

### Study burden and risks

Burden: 10 ml extra blood is taken
Risks: no extra risks

## 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

1) Admission with suspected Community Acquired Pneumonia
2) Age: adult (18 years and older)
3) Informed consent

## Exclusion criteria

1. Recent admission (<2 weeks), or living in nursing home
2. History of bronchial obstruction or postobstruction pneumonia. Patients with COPD will not be excluded.
3. History of lungcancer or pulmonary metastases
4. AIDS, known or suspected pneumonia caused by Pneumocystis Carinii or known or suspected active tuberculosis.
5. Unability to give informed consent.

# Study design

## Design

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

## Recruitment

NL
Recruitment status: Recruitment stopped

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|---|---|
| Start date (anticipated): | 15-01-2008 |
| Enrollment: | 1400 |
| Type: | Actual |

## Ethics review

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| Approved WMO Date: | 27-11-2007 |
| Application type: | First submission |
| Review commission: | METC Universitair Medisch Centrum Utrecht (Utrecht) |
| Approved WMO Date: | 05-02-2008 |
| 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 | NL18747.041.07 |