

Is beta-lactam therapy, until the patient has been afebrile for 48 hours (at least 5 days), sufficient for the treatment of community-acquired pneumonia?

Submission date 19/01/2006	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 07/02/2006	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 22/03/2006	Condition category Respiratory	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

N/A

Study information

Scientific Title

Acronym

PNEITID

Study objectives

Is beta-lactam therapy until the patient has been afebrile for 48 hours (and been treated for at least 5 days) as effective as beta-lactam therapy for 10 days in uncomplicated community-acquired pneumonia?

Ethics approval required

Old ethics approval format

Ethics approval(s)

Yes, by the Ethics Committee of the Orebro County Council, number 965-1999 (Sweden)

Study design

Prospective, randomised, open-label, multi-center (4 centres) study

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Health condition(s) or problem(s) studied

Community-acquired pneumonia

Interventions

Patients who experience improvement with beta-lactam monotherapy are randomised, on treatment day 2-5, to receive this medication for either 10 days or until he/she has been afebrile for 48 hours (and has been treated for at least 5 days).

The body temperature is measured rectally three times daily and the patient is considered afebrile after a second consecutive temperature read at $\leq 37.8^{\circ}\text{C}$. Two weeks from the start of antibiotic treatment, a study nurse will have a telephone conversation with the patient, and four weeks from start of treatment, a follow-up visit, including a chest X-ray, is performed.

At hospital discharge, at the telephone conversation, and at the follow-up visit, the patient is asked if he/she has experienced cough or fever and is asked to describe his/her physical and mental condition. C-reactive protein and a serum for serological tests are taken on treatment day 3 and at the follow-up visit. Serological tests for *Mycoplasma pneumoniae*, *Chlamydia pneumoniae*, *Chlamydia psittaci*, and other respiratory viruses are performed.

At presentation, patients suitable for the study are subjected to cultures from blood, sputum, and nasopharyngeal secretions. Since 2005, the Binax NOW® *Streptococcus pneumoniae* urinary antigen test is also used to establish the pneumonia aetiology.

If a patient experiences fever, increasing dyspnoea, or increasing cough during the first month after inclusion in the study, careful analysis, including radiological investigations, microbiological investigations, and other laboratory investigations, is performed.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

beta-lactam

Primary outcome measure

1. Clinical cure at the four-week-visit
2. Recurrence of pneumonia within one month

Secondary outcome measures

1. Resolution of X-ray infiltrates
2. C-reactive protein-level at the four-week-visit
3. Reported fever, cough and of physical and mental condition at the telephone conversation or at the follow-up visit

Overall study start date

01/12/1999

Completion date

31/05/2007

Eligibility

Key inclusion criteria

Adult patients with uncomplicated febrile community-acquired pneumonia, with chest X-ray infiltrates, who initially experience improvement with beta-lactam monotherapy

Participant type(s)

Patient

Age group

Adult

Sex

Both

Target number of participants

200

Key exclusion criteria

Nursing home resident, hospitalisation during the preceding month, antibiotic treatment for any reason during the preceding week, ongoing antipyretic medication. Inability to make a telephone conversation or to attend to a follow-up visit

Date of first enrolment

01/12/1999

Date of final enrolment

31/05/2007

Locations

Countries of recruitment

Sweden

Study participating centre

Department of Infectious Diseases

Orebro

Sweden

SE-70185

Sponsor information

Organisation

The Research Committee of Orebro County Council (Sweden)

Sponsor details

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Sponsor type

Research organisation

ROR

<https://ror.org/00maqj547>

Funder(s)

Funder type

Research organisation

Funder Name

The Research Committee of Orebro County Council and The Orebro University Hospital Research Foundation (Sweden)

Results and Publications

Publication and dissemination plan

Not provided at time of registration

Intention to publish date**Individual participant data (IPD) sharing plan****IPD sharing plan summary**

Not provided at time of registration

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Other publications	Stralin et al. Clinical Infectious Diseases, ;38: 766-7.	01/03/2004		Yes	No