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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

Registration date
07/02/2006

Last Edited
22/03/2006

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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 =/< 37.8 °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, Chlamydophila pneumoniae, Chlamydophila 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