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Procalcitonin guided reduction of the duration of antibiotic therapy in Community Acquired Pneumonia

Submission date	Recruitment status	[_] Prospectively registered
18/01/2005	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
15/02/2005	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
19/11/2007	Respiratory	

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
EKBB 232/03

Study information

Scientific Title

Acronym
ProCAP-Study/ProResp II-Study

Study objectives
In patients with Community Acquired Pneumonia (CAP), guidelines recommend antibiotic treatment for 7 to 21 days. Procalcitonin is elevated in bacterial infections, and its dynamics have prognostic implications.

Objective:
To assess procalcitonin guidance for the initiation and duration of antibiotic therapy in community-acquired pneumonia.

Hypothesis:
Procalcitonin guidance could significantly shorten antibiotic duration with a similar clinical and laboratory outcome.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The study was approved by the institutional review board of University Hospital Basel. Written, informed consent was obtained from all included patients or their legal representatives.

Study design
Randomised controlled trial

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 (CAP)

Interventions

Control group:
Receive antibiotics according to usual practice.

Intervention group:
In the procalcitonin group, antibiotic treatment was based on serum procalcitonin concentrations as follows:
1. Strongly discouraged: less than 0.1 µg/L
2. Discouraged: less than 0.25 µg/L
3. Encouraged: greater than 0.25 µg/L
4. Strongly encouraged: greater than 0.5 µg/L

Reevaluation of the clinical status and measurement of serum procalcitonin levels was recommended after 6 - 24 hours in all patients from whom antibiotics were withheld. Procalcitonin levels were reassessed after 4, 6, and 8 days. Antibiotics were discontinued on the basis of the procalcitonin cutoffs defined above. In patients with very high procalcitonin values on admission (e.g., greater than 10 µg/L), discontinuation of antibiotics was encouraged if levels decreased to levels less than 10% of the initial value (e.g., 1 µg/L, instead of less than 0.25 µg/L).

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Total antibiotic use, recorded on days 4, 6, and 8 and at follow-up after 6 weeks.

Secondary outcome measures
Measures of laboratory and clinical outcomes, recorded on days 4, 6, and 8 and at follow-up after 6 weeks.

Overall study start date
01/01/2004

Completion date
31/12/2005

Eligibility

Key inclusion criteria
The criterion for inclusion in the study was a suspected CAP as the main diagnosis. This was defined as presence of a new infiltrate on chest X-ray accompanied by one or several acquired respiratory symptoms and signs:
1. Cough
2. Sputum production
3. Dyspnoea
4. Fever over 38.0°C
5. Auscultatory findings of abnormal breath sounds and rales
6. Leukocytosis more than 10 x 10^9 cells/L or leukopenia less than 4 x 10^9 cells/L in the absence of a hospital stay within 14 days before admission

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
250

Key exclusion criteria
1. Cystic fibrosis or active tuberculosis
2. Immunocompromised patients, i.e. patients infected with Human Immunodeficiency Virus (HIV) infection and a CD4 count below 200
3. Neutropenic patients with a neutrophil count less than 500 x 10^9/ml
4. Under chemotherapy with neutrophils 500 - 1000 x 10^9/ml with an expected decrease to values less than 500 x 10^9/ml
5. Immunosuppressive therapy after bone marrow or solid organ transplantation
6. Nosocomial pneumonia

Date of first enrolment
01/01/2004

Date of final enrolment
31/12/2005

Locations

Countries of recruitment
Switzerland

Study participating centre
University Hospital
Basel
Switzerland
4031

Sponsor information

Organisation
University Hospital Basel (Switzerland)

Sponsor details

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Sponsor type
Hospital/treatment centre

Website
http://www.universitaetsspital-basel.ch/

ROR
https://ror.org/04k51q396

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospital Basel (Switzerland):

Funder Name
1. Clinic of Pulmonary Medicine

Funder Name
2. Clinic of Endocrinology

Funder Name
3. Emergency Unit

Funder Name
4. Department of Internal Medicine

Funder Name

5. Department of Central Laboratories (infrastructure)

Funder Name
BRAHMS AG (Germany) - assay material

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?
Results article		28/06/2006		Yes	No
Other publications		01/07/2006		Yes	No
Other publications		01/11/2007		Yes	No