

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

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

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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Additional identifiers

Protocol serial number
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.

Primary study design

Interventional

Study design

Randomised controlled trial

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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 10×10^9 cells/L or leukopenia less than 4×10^9 cells/L in the absence of a hospital stay within 14 days before admission

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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 500×10^9 /ml

4. Under chemotherapy with neutrophils $500 - 1000 \times 10^9/\text{ml}$ with an expected decrease to values less than $500 \times 10^9/\text{ml}$
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)

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

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