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Procalcitonin-guided antibiotic therapy in acute exacerbations of chronic obstructive pulmonary disease (COPD) (AECOPD): a randomised trial - The ProCOLD Study

Submission date
24/03/2005

Recruitment status
No longer recruiting

Registration date
10/05/2005

Overall study status
Completed

Last Edited
12/08/2013

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Acronym
PROCOLD

Study objectives
This study aimed to evaluate the outcome of acute exacerbations of COPD (AECOPD) comparing a standard with a procalcitonin (PCT)-guided antibiotic approach.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Not provided at time of registration

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
Acute exacerbations of chronic obstructive pulmonary disease (COPD)

Interventions
At presentation patients will be randomly assigned to the procalcitonin-guided therapy group or to the standard-group. In the ProCT-group, antibiotic therapy will be discouraged (ProCT less than 0.1 ng/ml) or encouraged (ProCT greater than 0.25 ng/ml) based on ProCT levels. In the standard group therapy will be left to the discretion of the treating physician. A standardised work-up including C-reactive protein (CRP), white blood cell count (WBC), sputum /bronchoalveolar lavage (BAL) bacteriology, viral serology, blood cultures, spirometry, chest x-ray and clinical parameters will be undertaken. After 6 months, all patients will be re-evaluated in regard to clinical and laboratory parameters, spirometry and number of AECOPD.

Intervention Type
Other

Phase
Not Specified

Primary outcome measure
Antibiotic use (% of patients).

Secondary outcome measures
1. Measures of laboratory and clinical outcome, i.e., serum ProCT and plasma C-reactive protein levels, leukocyte counts, temperature, oxygen saturation, respiratory rate, pulse rate, blood pressure, quality of life indices, length of hospitalisation, complications during the course of disease until follow-up in 14 - 21 days (i.e. need for intensive care unit [ICU] stay, death)
2. Recurrence of exacerbation within 6 months after inclusion in the study including hospitalisation, antibiotics and oral steroids need

Overall study start date
23/11/2003

Completion date
31/05/2005

Eligibility

Key inclusion criteria
Patients presenting an acute exacerbation of COPD requiring medical therapy in the emergency station of a university hospital in Switzerland.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
200

Key exclusion criteria
Immunosuppression.

Date of first enrolment
23/11/2003

Date of final enrolment
31/05/2005

Locations

Countries of recruitment
Switzerland

Study participating centre
University Hospital Basel
Basel
Switzerland
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Sponsor information

Organisation
University Hospital Basel (Switzerland)

Sponsor details
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Sponsor type
Hospital/treatment centre

ROR
https://ror.org/04k51q396

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
University Hospital Basel, Pneumology Department (Switzerland)

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	results	01/01/2007		Yes	No