

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	<input type="checkbox"/> Prospectively registered
Registration date 10/05/2005	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 12/08/2013	Condition category Respiratory	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
		<input type="checkbox"/> 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

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

Study type(s)

Treatment

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(s)

Antibiotic use (% of patients).

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

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, Pneumology Department (Switzerland)

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	results	01/01/2007		Yes	No