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

Submission date	Recruitment status	Prospectively registered		
24/03/2005  Registration date	No longer recruiting  Overall study status	☐ Protocol		
		Statistical analysis plan		
10/05/2005	Completed	[X] Results		
<b>Last Edited</b> 12/08/2013	Condition category Respiratory	[] Individual participant data		

#### Plain English summary of protocol

Not provided at time of registration

#### Contact information

#### Type(s)

Scientific

#### Contact name

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#### Additional identifiers

**Protocol serial number** 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

#### 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