

# Additional antibiotics for acute bacterial exacerbation of chronic obstructive pulmonary disease

<b>Submission date</b> 04/02/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 19/03/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 21/06/2010	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**

N/A

## Study information

### Scientific Title

Randomised, double-blind, multi-centre, placebo-controlled study to evaluate the efficacy of 6-day additional oral moxifloxacin administration 400 mg once a day (qd) after common antibiotic treatment on acute bacterial exacerbation of chronic obstructive pulmonary disease patients

### Acronym

AAABC study

### Study objectives

Additional antibiotics administration in bacteria exacerbation of chronic obstructive pulmonary disease (COPD) inpatients after common antibiotics treatment will decrease the incidence of acute exacerbations by lowering the bacterial burden.

### Ethics approval required

Old ethics approval format

### Ethics approval(s)

Ethics Committee for Biomedical Research Projects, West China Hospital, Sichuan University, approved on 17/02/2009 (ref: NO 3, 2009)

### Study design

Randomised placebo-controlled double-blind multi-centre trial

### Primary study design

Interventional

### Secondary study design

Randomised controlled trial

### Study setting(s)

Hospital

### Study type(s)

Treatment

### Participant information sheet

Please contact Miss Yufang Huang (loveflower404@163.com) to request a patient information sheet.

### Health condition(s) or problem(s) studied

Acute bacterial exacerbations in chronic obstructive pulmonary disease (COPD)

### Interventions

Intervention group: Moxifloxacin (oral) 400 mg once a day (qd) for 6 days  
Control group: Placebo

Subjects, caregivers, investigators and outcomes assessors will all be blinded to the treatment allocation.

As of 21/06/2010 this record has been updated to include an extended anticipated end date; the initial anticipated end date at the time of registration was 01/07/2010.

### **Intervention Type**

Other

### **Phase**

Not Applicable

### **Primary outcome measure**

The following will be followed-up for one year:

1. Time to acute exacerbation
2. Incidence of total acute exacerbation

### **Secondary outcome measures**

The following will be assessed at 14 and 30 days from end of interventions, then every two months for one year:

1. Changes in lung function (Forced expiratory volume in 1 second [FEV1], FEV1/Forced vital capacity [FVC])
2. The BODE index: Body Mass Index(B), Airflow obstruction (O), Dyspnoea(D), Exercise capacity index(E)

### **Overall study start date**

18/02/2009

### **Completion date**

01/07/2012

## **Eligibility**

### **Key inclusion criteria**

1. Both males and females, 45-80 years old
2. History of COPD (Global Initiative for chronic Obstructive Lung Disease [GOLD] 2006 criteria)
3. Moderate to severe COPD (GOLD 2006 criteria)
4. Have at least one acute exacerbation episodes in the proceeding year
5. Clinical evidence of acute bacteria exacerbations of COPD. Patient must meet criterion 5.1 below plus one of the other four criteria to be eligible:
  - 5.1. Production of purulent sputum as defined by gramstained sputum specimen
  - 5.2. Increased dyspnoea
  - 5.3. Increased sputum production
  - 5.4. Fever
  - 5.5. Increased white blood cells (WBC) or neutrophilic granulocyte portion

### **Participant type(s)**

Patient

### **Age group**

**Adult**

**Sex**

Both

**Target number of participants**

80

**Key exclusion criteria**

1. Extremely severe acute exacerbation of chronic obstructive pulmonary disease (AECOPD)
2. Comply with pulmonary encephalopathy
3. Heart failure, acute coronary artery syndrome
4. Gastrointestinal (GI) bleeding
5. Need for mechanical ventilation
6. History of hypersensitivity to fluoroquinolones
7. Creatinine (Cr)  $\geq 1 \times$  upper limit of normal (ULN), blood urea nitrogen (BUN)  $\geq 1 \times$  ULN, aspartate aminotransferase (AST), alanine aminotransferase (ALT)  $\geq 5 \times$  ULN or total bilirubin  $\geq 3 \times$  ULN at screening
8. Other chronic respiratory disease that lead to decline in pulmonary function, such as pneumonia, cancer, asthma, bronchiectasis, diffused lung interstitial fibrosis
9. Infection that is not because of pulmonary or bronchial tree
10. Use of systemic glucocorticoid (prednisolone  $>10$  mg/d or other corticoid equal to this) within 30 days

**Date of first enrolment**

18/02/2009

**Date of final enrolment**

01/07/2012

## **Locations**

**Countries of recruitment**

China

**Study participating centre**

**West China Hospital**

Chengdu

China

610041

## **Sponsor information**

**Organisation**

West China Hospital, Sichuan University (China)

**Sponsor details**

c/o Prof Chuntao Liu  
Respiratory Department  
NO37 Outer-south  
Guoxue Alley  
Chengdu  
China  
610041

**Sponsor type**

Hospital/treatment centre

**Website**

<http://eng.cd120.com/>

**ROR**

<https://ror.org/007mrxy13>

**Funder(s)****Funder type**

Other

**Funder Name**

Investigator initiated and funded (China)

**Funder Name**

Bayer Health Care/ Bayer Schering Pharma (China)

**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