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Additional antibiotics for acute bacterial exacerbation of chronic obstructive pulmonary disease

Submission date 04/02/2009	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 19/03/2009	**Overall study status** Completed	
Last Edited 21/06/2010	**Condition category** Respiratory	

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
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 gramistained 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 cornary artery syndrome
4. Gastrointestimal (GI) bleeding
5. Need for mechanical ventilation
6. History of hypersensitivity to fluoroquinolones
7. Creatinine (Cr) >=1 x upper limit of normal (ULN), blood urea nitrogen (BUN) >=1 x ULN, aspartate aminotransferase (AST), alanine aminotransferase (ALT) >= 5 x ULN or total bilirubin >=3 x 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
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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