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Calrithromycin versus first-line antibiotics for acute chronic obstructive pulmonary disease (COPD)

Submission date 18/11/2005	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 18/11/2005	**Overall study status** Completed	
Last Edited 03/03/2009	**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
MCT-63144

Study information

Scientific Title
A randomised trial comparing clarithromycin to first-line antibiotics for the out-patient treatment of acute chronic obstructive pulmonary disease (COPD)

Acronym
COPD

Study objectives
Primary objectives:
To determine whether a 10-day course of oral antibiotics, given to patients with acute exacerbations of COPD on discharge from the emergency department will have an effect on the proportion of patients who relapse within 30 days of presentation.

Secondary objectives:
1. To determine whether the proportion of patients who relapse within 10 days will be lower in the macrolide-treated group
2. To determine whether macrolides will improve airflow obstruction (forced expiratory volume in one second [FEV1]) to a greater extent than placebo over the 30 day treatment period
3. To determine whether improvements in subjective dyspnoea scores and disease-specific, health-related quality of life will be greater in macrolide-treated patients
4. To determine whether macrolides will have an effect on the proportion of patients who require hospitalisation within 30 days of presentation
5. To compare rates of adverse effects among the macrolide and doxycycline groups.

Ethics approval required
Old ethics approval format

Ethics approval(s)
University of Alberta, Edmonton, Alberta, Health Research Ethics Board gave approval on 23rd May 2003

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 chronic obstructive pulmonary disease (COPD)

Interventions
All patients receive prednisone (40 mg/day x 10 days), Combivent inhaler, and an Aerochamber for inhaler delivery. Patients are randomised to receive clarithromycin (Biaxin- XL) or doxycycline in a double-blind, double dummy fashion.

Trial details received 12 Sept 2005

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Clarithromycin, doxycycline

Primary outcome measure
The proportion of patients who relapse in the two treatments groups within 30 days of entry into the trial

Secondary outcome measures
1.The absolute and percent change in post-bronchodilator FEV1 on study day 10 and day 30 compared to day 1
2. Improvement in subjective dyspnoea score as assessed by the baseline and transitional Dyspnoea Indexes
3. Improvement in disease-specific quality of life as assessed by the Chronic Respiratory Disease Index Questionnaire (CRQ)
4. Proportion of patients hospitalised (and their length of stay data) within 30 days
5. Adverse effect rates assessed at 10 days

Overall study start date
01/11/2003

Completion date
30/04/2006

Eligibility

Key inclusion criteria
1. Patients must have had a previous diagnosis of chronic bronchitis, emphysema or COPD established by their physician
2. Patients must have evidence of airflow obstruction on presentation at the emergency department, defined as an FEV1 less than or equal to 70% of predicted and a FEV1/forced vital capacity (FVC) ratio less than or equal to 70%
3. Patient must be greater than or equal to 35 years old, either sex

4. Patients must have a minimum history of 15 pack-years of smoking
5. Patients must be experiencing an acute exacerbation of COPD and must meet at least two of the following three clinical criteria for acute COPD exacerbation as defined by Anthonisen: increased chronic baseline dyspnoea, increased sputum volume or increased sputum purulence. The above complaints had to have necessitated the ED visit.

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
270

Key exclusion criteria
1. Physician diagnosed asthma (before age 40)
2. Use of oral or injectable antibiotics during the 10 days preceding trial entry
3. Patients with a history of bronchiectasis or cystic fibrosis will be excluded
4. Pneumonia or congestive heart failure on emergency room chest radiography
5. Patients not able to perform spirometry assessment
6. Patients with known adverse reaction or intolerance to macrolides or doxycycline
7. Inability to provide informed consent or comply with the study protocol due to cognitive impairment, language barrier, or distance greater than 100 km from the study centre
8. Patients admitted to hospital
9. Patients has previously participated in the study

Date of first enrolment
01/11/2003

Date of final enrolment
30/04/2006

Locations

Countries of recruitment
Canada

Study participating centre
University of Alberta Hospital
Edmonton
Canada
T6G 2B7

Sponsor information

Organisation
University of Alberta (Canada) - Faculty of Medicine and Dentistry

Sponsor details
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Sponsor type
University/education

Website
http://www.med.ualberta.ca/Home/index.cfm

ROR
https://ror.org/0160cpw27

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-63144)

Funder Name
Abbott (USA)

Funder Name
Boehringer-Ingelheim (USA)

Alternative Name(s)
Boehringer Ingelheim Pharmaceuticals, Inc., Boehringer Ingelheim International GmbH, BI, BIPI

Funding Body Type
Private sector organisation

Funding Body Subtype
For-profit companies (industry)

Location
United States of America

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?
Abstract results	p184	01/05/2007		No	No
Abstract results	S13	01/05/2008		No	No