

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
Registration date 18/11/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 03/03/2009	Condition category Respiratory	☐ 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

Protocol serial number
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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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

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

Healthy volunteers allowed

No

Age group

Adult

Sex

All

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

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

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