

Multiple combination bactericidal antibiotics testing for acute exacerbations of cystic fibrosis associated with multi-resistant *Burkholderia cepacia* and *Pseudomonas aeruginosa* infection

Submission date 17/06/2005	Recruitment status No longer recruiting	☐ Prospectively registered ☐ Protocol
Registration date 22/06/2005	Overall study status Completed	☐ Statistical analysis plan ☒ Results
Last Edited 03/10/2017	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-44147

Study information

Scientific Title

Multiple combination bactericidal antibiotics testing for acute exacerbations of cystic fibrosis associated with multi-resistant *Burkholderia cepacia* and *Pseudomonas aeruginosa* infection: a randomised controlled trial

Study objectives

The objective of this clinical trial is to prospectively assess whether the use of combination antibiotic therapy, directed by results from multiple combination, bactericidal antibiotic testing (MCBT), improves bacteriologic and clinical outcomes in patients with acute pulmonary exacerbations of cystic fibrosis who are infected with multiple resistant bacteria.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval gained from the Ottawa Hospital Research Ethics Board in Spring 2000

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Pulmonary exacerbation in adult patients with cystic fibrosis (CF)

Interventions

Patients randomised to the control group will receive a 14 days course of any two intravenous antibiotics $\pm$ one inhaled antibiotic (tobramycin/TOBI) chosen by their physicians based on usual culture and sensitivity testing.

Patients randomised to MCBT-directed therapy group will receive a 14 days course of any two intravenous antibiotics $\pm$ one inhaled antibiotic (tobramycin/TOBI) chosen based on MCBT culture and sensitivity testing.

Intervention Type

Drug

Phase

Not Applicable

Drug/device/biological/vaccine name(s)

Antibiotics

Primary outcome(s)

The time (days) from randomisation until the patient's next pulmonary exacerbation.

Key secondary outcome(s)

1. Mean changes in sputum bacterial densities for day zero to day 14
2. Changes in pulmonary function, pre-bronchodilator forced expiratory volume in one second (FEV1), and forced vital capacity (FVC)
3. Changes in oxygenation from day zero to day 14
4. The proportion of antibiotic treatment failures in both treatment groups within 14 days
5. Changes in subjective dyspnoea score from day zero to day 14
6. Length of hospital stay, for patients admitted to hospital
7. Adverse effects related to antibiotic therapy

Completion date

15/02/2005

Eligibility**Key inclusion criteria**

1. Age greater than or equal to 12, either sex
2. A confirmed diagnosis of cystic fibrosis (a sweat chloride value higher than 60 mmol/litre or two disease-causing mutations)
3. Chronically colonised with multi-resistant *P. aeruginosa*, or *S. maltophilia*, or *A. xylosoxidans* (at least two sputum cultures within the last 12 months which have grown these multi-resistant bacteria, one of which must have been obtained within six months of randomisation)
4. Patients must be known to be chronically colonised with *Burkholderia cepacia* bacteria (at least two sputum cultures within the last 12 months which have grown *Burkholderia cepacia*, one of which must have been obtained within six months of randomisation)
5. Patients must be able to spontaneously produce sputum for culturing

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Key exclusion criteria

1. Unable to give informed consent
2. Previous lung transplant recipients
3. Patients with severe pulmonary exacerbations who require admission to an Intensive Care Unit (ICU) and/or mechanical ventilatory support
4. Patients who are already receiving continuous home intravenous antibiotic therapy
5. Pregnant patients

Date of first enrolment

03/08/2000

Date of final enrolment

15/02/2005

Locations

Countries of recruitment

Canada

Study participating centre

The Ottawa Hospital

Ottawa, Ontario

Canada

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Sponsor information

Organisation

Ottawa Hospital Research Institute (Canada)

ROR

<https://ror.org/03c62dg59>

Funder(s)

Funder type

Research organisation

Funder Name

Canadian Institutes of Health Research (CIHR) (Canada) - <http://www.cihr-irsc.gc.ca> (ref: MCT-44147)

Funder Name

Other funders:

Funder Name

1. Canadian Cystic Fibrosis Foundation (Canada)

Funder Name

2. Astra Zeneca Canada Inc. (Canada)

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	01/08/2005		Yes	No