ISRCTN60187870 https://doi.org/10.1186/ISRCTN60187870

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

Registration date
22/06/2005

Overall study status
Completed

Last Edited
03/10/2017

Condition category
Respiratory

[_] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

Primary study design
Interventional

Study design
Randomised controlled trial

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 ± 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 ± 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. xylosidans (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
K1H 8L6

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