ISRCTN51767272 https://doi.org/10.1186/ISRCTN51767272

A randomised trial of empiric broad-spectrum antibiotics and invasive diagnostic techniques in the setting of Ventilator-Associated Pneumonia

Submission date
09/09/2005

Recruitment status
No longer recruiting

Registration date
09/09/2005

Overall study status
Completed

Last Edited
11/12/2007

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-50377

Study information

Scientific Title

Acronym
VAP

Study objectives
To evaluate whether the use of two empiric broad-spectrum antibiotics and invasive diagnostic techniques will improve clinical resolution, decrease length of stay and reduce mortality of critically ill patients with a clinical suspicion of late Ventilator-Associated Pneumonia (VAP).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from the Queen's University Health Sciences & Affiliated Teaching Hospitals Research Ethics Board on the 12th October 1999.

Study design
Randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Clinical suspicion of ventilator associated pneumonia in critically ill patients

Interventions
Patients will undergo bronchoscopy with bronchoalveolar lavage or endotracheal aspirates. Following sampling patients will be randomised again to receive either meropenem and ciprofloxacin or meropenem alone.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Broad-spectrum antibiotics

Primary outcome(s)
Mortality at 28 days.

Key secondary outcome(s))
1. Duration of stay in ICU
2. Adjudicated diagnosis of pneumonia
3. Clinical and microbiological response to treatment

4. Adequacy of initial treatment
5. Emergence of resistant organisms
6. Candida colonization and infection
7. Multiple organ dysfunction
8. Duration of mechanical ventilation
9. Hospital length of stay
10. Antibiotic use and costs of care

Completion date
30/09/2004

Eligibility

Key inclusion criteria
1. Adult patients greater than or equal to 16 years old, either sex
2. Greater than 96 hours in the Intensive Care Unit (ICU)
3. Mechanically ventilated (greater than or equal to 48 hours)
4. Develops a clinical suspicion of pneumonia while ventilated

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
All

Key exclusion criteria
1. Unstable candidate for bronchoscopy as defined by the bronchoscopist
2. Patients not expected to survive greater than 72 hours or anticipate withdrawing treatments within 72 hours from the point of randomisation
3. Known or suspected history of anaphylaxis to penicillins, cephalosporins, carbapenems, meropenem or ciprofloxacin
4. Women who are pregnant or lactating
5. Patients already infected or colonised (respiratory tract only) with an organism not sensitive to study drugs
6. Patients already infected with pseudomonas species
7. Already on study drugs
8. Immunocompromised (post-organ transplantation, Human Immunodeficiency Virus [HIV], neutropenic [less than 1000 absolute neutrophils], corticosteroids [greater than 20 mg/day of prednisone or equivalent for more than 6 months])
9. Prior randomisation in this study
10. Enrolment in other interventional study

Date of first enrolment
01/05/2000

Date of final enrolment
30/09/2004

Locations

Countries of recruitment
Canada

Study participating centre
Kingston General Hospital
Kingston
Canada
K7L 2V7

Sponsor information

Organisation
Queens University (Canada)

ROR
https://ror.org/02y72wh86

Funder(s)

Funder type
Research organisation

Funder Name
Canadian Institutes of Health Research (CIHR) (Canada) - http://www.cihr-irsc.gc.ca (ref: MCT-50377)

Funder Name
Physician Services Inc. (PSI) (Canada)

Funder Name
Bayer (Canada)

Funder Name
AstraZeneca (Canada)

Alternative Name(s)
AstraZeneca PLC, Pearl Therapeutics, AZ

Funding Body Type
Government organisation

Funding Body Subtype
For-profit companies (industry)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	Results	21/12/2006		Yes	No