ISRCTN31976779 https://doi.org/10.1186/ISRCTN31976779

Combination therapy versus monotherapy: a randomised study on the evolution of inflammatory parameters after ventilator associated pneumonia

Submission date
22/12/2005

Recruitment status
No longer recruiting

Registration date
11/01/2006

Overall study status
Completed

Last Edited
25/09/2009

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

Contact name
Prof Pierre Damas

Contact details
General Intensive Care Department
University Hospital
Domaine Universitaire du Sart-Tilman
Liege
Belgium
4000
+32 (0)4 366 74 95
pdamas@chu.ulg.ac.be

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title

Study objectives
Does a combination antibiotic therapy of ventilator associated pneumonia improve the inflammatory parameters faster than a monotherapy?

Ethics approval required
Old ethics approval format

Ethics approval(s)
Yes; 27/02/02; 2002/32

Study design
Randomised unblinded comparative study

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
Ventilator associated pneumonia

Interventions
Comparison between treatment with cefepime alone and cefepime associated with amikacin or levofloxacin

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)

Cefepime, amikacin, levofloxacin

Primary outcome measure
Time course evolution of C-reactive protein (CRP) levels, temperature and leucocytosis

Secondary outcome measures
1. Length of ventilatory support
2. Evolution of PaO2/FiO2
3. Mortality

Overall study start date
01/04/2002

Completion date
31/12/2003

Eligibility

Key inclusion criteria
Adult patients with ventilator associated pneumonia

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
150

Key exclusion criteria
1. Patients treated for other infection
2. Immunocompromised patients
3. Patients with life expectancy less than 72 hours

Date of first enrolment
01/04/2002

Date of final enrolment
31/12/2003

Locations

Countries of recruitment
Belgium

Study participating centre
General Intensive Care Department
Liege
Belgium
4000

Sponsor information

Organisation
Domaine Universitaire du Sart-Tilman (Belgium)

Sponsor details
Department of General Intensive Care
University Hospital
Domaine Universitaire du Sart-Tilman
Liege
Belgium
4000
pdamas@chu.ulg.ac.be

Sponsor type
University/education

ROR
https://ror.org/00afp2z80

Funder(s)

Funder type
University/education

Funder Name
Domaine Universitaire du Sart-Tilman (Belgium)

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?
Results article	results	01/01/2006		Yes	No