

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

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| Submission date 22/12/2005 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol |
| Registration date 11/01/2006 | Overall study status Completed | <input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results |
| Last Edited 25/09/2009 | Condition category Respiratory | <input type="checkbox"/> 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

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

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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 |