

Multicentric, randomized, comparative, open-labeled trial of a fixed dose combination of cefepime and amikacin versus cefepime alone in nosocomial pneumonia

Submission date 06/06/2006	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 23/06/2006	Overall study status Completed	☐ Protocol
Last Edited 08/01/2021	Condition category Infections and Infestations	☐ Statistical analysis plan
		☒ Results
		☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

Prof K.C Mohanty

Contact details

Professor and Head
K.J.Somaiya Medical Hospital and Research Centre
Department of Chest Medicine
Mumbai
India
400022

Additional identifiers

Protocol serial number

06-PLCT-CT-00037

Study information

Scientific Title

Multicentric, randomized, comparative, open-labeled trial of a fixed dose combination of cefepime and amikacin versus cefepime alone in nosocomial pneumonia

Acronym

RCCT

Study objectives

The objective of the trial was to compare the efficacy and safety of cefepime and amikacin fixed dose combination with cefepime alone in patients with nosocomial pneumonia.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approval given by Institutional Ethics Committee, reference number: Ct/ca/01

Primary study design

Interventional

Study design

Open-labeled, randomized controlled clinical trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Nosocomial pneumonia

Interventions

100 Patients were treated with cefepime and amikacin fixed-dose combination (FDC) 2.5 g twice a day (bid) and 100 patients received cefepime 2 g bid for 7-10 days

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

cefepime, amikacin

Primary outcome(s)

Outcome of therapy was based on clinical evaluation and bacteriological evaluation. Bacteriological evaluation was in terms of presence or absence of bacteria in sputum.

Key secondary outcome(s)

The cure rate was 65% in the cefepime and amikacin FDC group while clinical improvement was noticed in 24% of the patients. In the group treated with cefepime alone, the cure rate was 44%, while 27% showed clinical improvement. Mild adverse reactions were noticed in both groups.

Completion date

31/03/2006

Eligibility

Key inclusion criteria

Participants included were 200 patients infected with nosocomial pneumonia showing presence of pus cells more than 25 high power fields (HPF) and buccal epithelial cells less than 10 HPF

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

All

Total final enrolment

200

Key exclusion criteria

1. Hypersensitivity to cefepime, amikacin or related drugs
2. Children or adolescents less than 18 years of age
3. Pregnant women
4. Patients with renal or hepatic insufficiency
5. Patients not willing to give written informed consent

Date of first enrolment

01/11/2005

Date of final enrolment

31/03/2006

Locations

Countries of recruitment

India

Study participating centre**Professor and Head**

Mumbai

India

400022

Sponsor information

Organisation

Venus Remedies Limited (India)

ROR

<https://ror.org/0169rv113>

Funder(s)

Funder type

Industry

Funder Name

Venus Remedies Limited

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	01/05/2008	08/01/2021	Yes	No