

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

☐ Protocol

Registration date
23/06/2006

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
08/01/2021

Condition category
Infections and Infestations

☐ 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Study design

Open-labeled, randomized controlled clinical trial

Primary study design

Interventional

Secondary study design

Randomised controlled trial

Study setting(s)

Not specified

Study type(s)

Treatment

Participant information sheet

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 measure

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

Secondary outcome measures

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.

Overall study start date

01/11/2005

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

Age group

Adult

Sex

Both

Target number of participants

200

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)

Sponsor details

Intellectual Scientific Division

Research and Development Centre

51-52 Industrial Area

Phase-1

Panchkula

Haryana

India

134113

+91 17 22561244

operations@venusremedies.com

Sponsor type

Industry

Website

<http://www.venusremedies.com>

ROR

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

Funder(s)

Funder type

Industry

Funder Name

Venus Remedies Limited

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