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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

Registration date
23/06/2006

Last Edited
08/01/2021

Recruitment status
No longer recruiting

Overall study status
Completed

Condition category
Infections and Infestations

[_] 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
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Contact details
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India
400022

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

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