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Safety and efficacy of a fixed dose combination of cefepime and amikacin

Submission date	Recruitment status	[_] Prospectively registered
04/03/2008	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
15/05/2008	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
15/05/2008	Infections and Infestations	[_] Record updated in last year

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
Nex/VR/CT_PMS_089/01_2007

Study information

Scientific Title

An open labelled post marketing surveillance study to evaluate safety and efficacy of a fixed dose combination of cefepime and amikacin in subjects with mild to severe infections

Study objectives
To evaluate efficacy of fixed dose combination of cefepime-amikacin in various infections.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics approval received from:
1. Independent Ethic Committee for Clinical Research, New Delhi on the 11th April 2007 (ref: IEC /Nex/VR//CT-PMS/08901-2007)
2. Ethic Committee, SP Medical College and Associated Hospitals, Bikaner on the 16th July 2008 (ref: SP-EC//Nex/VR//CT-PMS/08901-2007)

Study design
Open labelled, randomised, multicentric clinical trial

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
Nosocomial pneumonia, febrile neutropenia, other bacterial infections

Interventions
The subjects were divided in three groups as per the severity of the infection:
1. Group A (severely infected) were given 2.5 g twice daily (BD) of cefepime-amikacin fixed dose combination (FDC)
2. Group B (moderately infected) were given 1.25 g BD of cefepime-amikacin FDC
3. Group C (mildly infected) were given 0.625 g BD of cefepime-amikacin FDC

Total duration of therapy 3 - 10 days, followed up for 7 days after the treatment.

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
Cefepime-amikacin

Primary outcome measure
Improvement in clinical and laboratory parameters, measured on day 0 and completion of treatment (COT) (i.e. day 5 - 7 or COT).

Secondary outcome measures
To observe incidence of adverse events as assessed by clinical evaluation and laboratory parameters, measured on day 0 and completion of treatment (COT) (i.e. day 5 - 7 or COT).

Overall study start date
28/04/2007

Completion date
14/09/2007

Eligibility

Key inclusion criteria
1. Hospitalised patients of either sex
2. Above 18 years of age
3. Clinically diagnosed subjects with moderate to severe infections of:
3.1. Febrile neutropenia (n = 110)
3.2. Nosocomial pneumonia (n = 110)
3.3. Other bacterial infection (n = 91)

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
315

Key exclusion criteria
1. History of hypersensitivity reaction or any specific contraindication to penicillin group of drugs
2. Hepatic or renal disorder or any heart disorder
3. Pregnancy and/or lactation
4. History of hearing loss
5. Alcoholics

Date of first enrolment

28/04/2007

Date of final enrolment
14/09/2007

Locations

Countries of recruitment
India

Study participating centre
Subharti Medical College
Merrut, UP
India
250002

Sponsor information

Organisation
Venus Remedies Limited (India)

Sponsor details
51-52 Industrial Area
Phase- I
Panchkula, Haryana
India
134113
research@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 (India)

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