

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

Submission date 04/03/2008	Recruitment status No longer recruiting	☐ Prospectively registered
		☐ Protocol
Registration date 15/05/2008	Overall study status Completed	☐ Statistical analysis plan
		☐ Results
Last Edited 15/05/2008	Condition category Infections and Infestations	☐ Individual participant data
		☐ 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

Protocol serial number

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

Study type(s)

Treatment

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(s)

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

Key secondary outcome(s)

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).

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

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

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)

ROR

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

Funder(s)

Funder type

Industry

Funder Name

Venus Remedies Limited (India)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration