Efficacy and safety of the fixed dose combination of cefepime and sulbactam

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

Contact name

Dr Nitin Rathod

Contact details

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Additional identifiers

Protocol serial number

venus/cefepime sulbactam/082006A

Study information

Scientific Title

Multicentric, open labelled, non-randomised, clinical trial to assess efficacy and safety of the fixed dose combination of cefepime and sulbactam in complicated upper and lower tract infections

Study objectives

The objectives were:

- 1. To study the efficacy of fixed dose combination of cefepime and sulbactam injections in in complicated upper and lower tract infections
- 2. To assess comaprative safety of study drug

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the National Ethic Committee, Ahembdabad on the 28th April 2007 (date of issue of letter: 2nd May 2007) (ref: NEC/04-2007/02/VENUS /CEFEPIME_SULBACTAM/082006A).

Study design

Open labelled, non-randomised, multicentric clinical trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Complicated upper and lower tract infections

Interventions

Fixed dose combination of cefepime and sulbactam (1.5 g to 3 g, intravenous [i.v.] twice daily). Duration of treatment 7 to 10 days, followed for 7 days after the treatment.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Cefepime, sulbactam

Primary outcome(s)

Improvement in clinical and laboratory parameters, measured on day 0, day 3 and day 7 (completion of treatment).

Key secondary outcome(s))

To observe incidence of adverse events as assessed by clinical evaluation and laboratory parameters, measured on day 0, day 3 and day 7 (completion of treatment).

Completion date

31/07/2007

Eligibility

Key inclusion criteria

- 1. Participants aged greater than 18 years (n = 102), either sex
- 2. Suffering from lower respiratory tract infections caused by gram negative organisms including pseudomonas aeruginosa

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 beta lactams
- 2. Presence of hepatic or renal disorders
- 3. Pregnancy or lactation
- 4. History of hearing loss
- 5. Alcoholics
- 6. Previous history seizure

Date of first enrolment

01/05/2007

Date of final enrolment

31/07/2007

Locations

Countries of recruitment

India

Study participating centre Dr R N Cooper Municipal General Hospital

Mumbai India 400056

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