

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

Submission date 04/03/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input type="checkbox"/> Protocol
Registration date 15/05/2008	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
Last Edited 15/05/2008	Condition category Infections and Infestations	<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> 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
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 complicated upper and lower tract infections
2. To assess comparative safety of study drug

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the National Ethic Committee, Ahmedabad 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

Secondary study design

Non randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet**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 measure

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

Secondary outcome measures

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).

Overall study start date

01/05/2007

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

102

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)

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