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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

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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 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

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
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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