ISRCTN02965214 https://doi.org/10.1186/ISRCTN02965214

Efficacy and safety of the fixed dose combination of ceftazidime and sulbactam in lower respiratory tract infections (LRTI)

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

Protocol serial number
venus/ceftazidime_sulbactam/082006A

Study information

Scientific Title

Multicentric, open labelled, non-randomised, clinical trial to assess efficacy and safety of the fixed dose combination of ceftazidime and sulbactam in lower respiratory tract infections caused by gram negative organisms including pseudomonas aeruginosa

Study objectives
The objectives were:
1. To study the efficacy of fixed dose combination of ceftazidime and sulbactam injections in lower respiratory tract infections caused by gram negative organisms including pseudomonas aeruginosa
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, Ahembdabad on the 28th April 2007 (date of issue of letter: 2nd May 2007) (ref: NEC/04-2007/03/VENUS /CEFTAZIDIME_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
Lower respiratory tract infections caused by gram negative organisms including pseudomonas aeruginosa

Interventions
Fixed dose combination of ceftazidime 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)
Ceftazidime, 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 = 104), 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 of seizures

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