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Efficacy and safety of the fixed dose combination of cefpirome 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

Protocol serial number
venus/cefpirome_sulbactam/082006A

Study information

Scientific Title
Multicentric, open labelled, non randomised, clinical trial to assess efficacy and safety of the fixed dose combination of cefpirome and sulbactam in bacteraemia/septicaemia and severe infections in intensive care patients

Study objectives
The objective of the trial was to study the efficacy of fixed dose combination of cefpirome and sulbactam injections in bacteraemia/septicaemia and severe infections in intensive care patients.

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/04-2007/04/VENUS /CEFPIROME_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
Bacteraemia/septicaemia and severe infections

Interventions
Fixed dose combination of cefpirome 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)
Cefpirome, sulbactam

Primary outcome(s)
Improvement in clinical and laboratory parameters, measured at 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 at 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 = 103), either sex
2. Suffering from bacteraemia/septicaemia and severe infections

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