

Ceftazidime tobramycin fixed drug combination (FDC) versus ceftazidime in lower respiratory tract infections

Submission date 04/03/2008	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 15/05/2008	Overall study status Completed	☐ Protocol
Last Edited 15/05/2008	Condition category Infections and Infestations	☐ Statistical analysis plan
		☐ Results
		☐ Individual participant data
		☐ 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_tobramycin/082006A

Study information

Scientific Title

Comparative efficacy and synergy establishment of ceftazidime tobramycin fixed drug combination (FDC) versus ceftazidime in lower respiratory tract infections

Study objectives

1. To assess efficacy of ceftazidime tobramycin fixed drug combination (FDC) in comparison with ceftazidime monotherapy in lower respiratory tract infections
2. To assess comparative safety of study drugs

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/04-2007/01/VENUS/TOBCEF/082006A).

Primary study design

Interventional

Study design

Open labelled, comparative, randomised, multicentric clinical trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Lower respiratory tract infections

Interventions

1. Ceftazidime (1 g) and tobramycin (120 mg) fixed drug combination (FDC), eight-hourly, intravenous (i.v.) for seven days
2. Ceftazidime (1 g), eight-hourly, i.v. for seven days

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Ceftazidime tobramycin fixed drug combination (FDC), ceftazidime alone

Primary outcome(s)

Improvement in clinical and laboratory parameters, measured on day 0 and day 7, followed up to 10 days after the treatment.

Key secondary outcome(s)

To observe incidence of adverse events as assessed by clinical evaluation and laboratory parameters, measured on day 0 and day 7, followed up to 10 days after the treatment.

Completion date

31/07/2007

Eligibility

Key inclusion criteria

1. Participants aged greater than 18 years (n = 240), either sex
2. Hospitalised patients suffering from lower respiratory tract infections

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Patients having received antibiotic treatment within two weeks of therapy
2. History of hypersensitivity reaction or any specific contraindication to beta lactams
3. Presence of hepatic or renal disorders
4. Pregnancy or lactation
5. History of hearing loss
6. Alcoholics
7. 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