ISRCTN69844323 https://doi.org/10.1186/ISRCTN69844323

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

| 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/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, Ahemdabad on the 28th April 2007 (date of issue of letter: 2nd May 2007) (ref: NEC/04-2007/01/VENUS/TOBCEF/082006A).

## Study design
Open labelled, comparative, randomised, multicentric clinical trial

## Primary study design
Interventional

## Secondary study design
Randomised controlled trial

## Study setting(s)
Hospital

## Study type(s)
Treatment

## Participant information sheet

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

### Secondary outcome measures
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.

### Overall study start date
01/05/2007

### Completion date
31/07/2007

## Eligibility

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

### Participant type(s)
Patient

### Age group
Adult

### Lower age limit
18 Years

### Sex
Both

### Target number of participants
240

### 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)

### Sponsor details
51 - 52 Industrial Area
Phase - 1
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