

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

<b>Submission date</b> 04/03/2008	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
<b>Registration date</b> 15/05/2008	<b>Overall study status</b> Completed	<input type="checkbox"/> Protocol
<b>Last Edited</b> 15/05/2008	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Statistical analysis plan
		<input type="checkbox"/> Results
		<input type="checkbox"/> Individual participant data
		<input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

Not provided at time of registration

## Contact information

### Type(s)

Scientific

### Contact name

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### Contact details

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## Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

### Secondary identifying numbers

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, Ahemdabad 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

## 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

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 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 = 104), 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**

104

**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)

**Sponsor details**

51 -52 Industrial Area

Phase - I

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