

# Efficacy and safety of the fixed dose combination of cefpirome and sulbactam

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

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## Additional identifiers

**EudraCT/CTIS number**

**IRAS number**

**ClinicalTrials.gov number**

**Secondary identifying numbers**  
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, Ahemdabad 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

**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**

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 measure**

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

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

103

**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)

**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