

Multicentric clinical trial on the efficacy and safety of ceftriaxone and sulbactam in lower respiratory tract infection

Submission date 08/06/2006	Recruitment status No longer recruiting	☐ Prospectively registered
Registration date 23/06/2006	Overall study status Completed	☐ Protocol
Last Edited 23/06/2006	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

Contact name

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Additional identifiers

Protocol serial number

CT/CS/01

Study information

Scientific Title

Study objectives

The increasing rate of the resistance of antibacterials in lower respiratory tract infection (LRTI) pathogens has resulted in the need to consider innovative approaches like combining β -lactam antibiotics with β -lactamase inhibitors. The presence of sulbactam in fixed-dose combination (FDC) along with ceftriaxone could extend the antibiotic spectrum of ceftriaxone to include bacteria normally resistant to it. The aim of our study was to evaluate the efficacy and safety of ceftriaxone and sulbactam in fixed-dose combination in the treatment of lower respiratory tract infection.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Independent institutional ethics committee approval of participating centres were taken before initiation, reference number: CT/CS/01

Study design

Open-label, non-comparative, multicentric study

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Lower respiratory tract infection

Interventions

Treatment consisted of 1 g ceftriaxone + 0.5 g sulbactam in intravenous fixed dose combination every eight hours for 7 -10 days

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Ceftriaxone, sulbactam

Primary outcome(s)

The overall efficacy of fixed dose combination (FDC) of ceftriaxone and sulbactam was excellent. The clinical cure rate was 77.14% and the bacteriological cure rate was 100%. A total of three adverse reactions were noted in 12 of the 105 patients receiving ceftriaxone and sulbactam

(FDC) but none of them warranted discontinuation of treatment. Adverse effects noted included: pain at the injection site (5.7%), superficial thrombophlebitis (4.76%), and mild diarrhea (0.95%).

Key secondary outcome(s)

Ceftriaxone and sulbactam in fixed dose combination (FDC) is an effective and well-tolerated antimicrobial agent that appears promising for the treatment of serious lower respiratory tract infections

Completion date

30/09/2005

Eligibility

Key inclusion criteria

1. Age ≥ 18 years
2. Fever $\geq 38^{\circ}\text{C}$
3. Sputum pus cells >25 high power fields (HPF)
4. Buccal epithelial cells <10 HPF

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

All

Key exclusion criteria

1. Hypersensitivity to ceftriaxone, sulbactam or related drugs
2. Children less than 18 years of age
3. Septicemic shock, active pulmonary malignancies, renal and hepatic insufficiencies

Date of first enrolment

01/04/2005

Date of final enrolment

30/09/2005

Locations

Countries of recruitment

India

Study participating centre
Manas Chest Clinic
Mumbai
India
400022

Sponsor information

Organisation
Venus Remedies Limited (India)

ROR
<https://ror.org/0169rv113>

Funder(s)

Funder type
Industry

Funder Name
Venus Remedies Limited

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not provided at time of registration