ISRCTN51896330 https://doi.org/10.1186/ISRCTN51896330

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

Submission date	Recruitment status	[_] Prospectively registered
08/06/2006	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
23/06/2006	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
23/06/2006	Infections and Infestations	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Milind Khadke

Contact details
Manas Chest Clinic
301 Marathon Chambers
P.K. Road
Paanchrasta
Mulund (W)
Mumbai
India
400022
milind_khadke@yahoo.com

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Multi-centre

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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 measure
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%).

Secondary outcome measures
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

Overall study start date
01/04/2005

Completion date
30/09/2005

Eligibility

Key inclusion criteria
1. Age ≥18 years
2. Fever ≥38°C
3. Sputum pus cells >25 high power fields (HPF)
4. Buccal epithelial cells <10 HPF

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
105

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)

Sponsor details
Intellectual Scientific Division
Research and Development Centre
51-52 Industrial Area
Phase-1
Panchkula
Haryana
India
134113
+91 17 22561244
operations@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

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