ISRCTN76443564 https://doi.org/10.1186/ISRCTN76443564

The efficacy and safety evaluation of ceftriaxone and sulbactam combination (1.5 gram) in patients with skin and soft tissue infections: an open label, parallel, randomized, prospective comparative trial

Submission date 25/05/2007	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [_] Record updated in last year
Registration date 27/06/2007	**Overall study status** Completed	
Last Edited 25/10/2021	**Condition category** Infections and Infestations	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Dr Pawanindra Lal

Contact details
Maulana Azad Medical College and Hospital
New Delhi
India
100012
+91 989 1209609
drplal@bol.net.in

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
CT/RX-PHARM/07

Study information

Scientific Title
The efficacy and safety evaluation of ceftriaxone and sulbactam combination (1.5 gram) in patients with skin and soft tissue infections: an open label, parallel, randomized, prospective comparative trial

Study objectives
To evaluate the efficacy and safety of ceftriaxone and sulbactam combination in patients with skin and soft tissue infections.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Dhanavantri Independent Ethics Committee (New Delhi), approved on 14th May 2007.

Study design
An open, parallel, randomised, prospective, comparative trial.

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Skin and soft tissue infections

Interventions
Intervention group: Ceftriaxone (1 gram) and sulbactam (0.5 gram) every 12 hours for maximum of 7 days
Control group: Ceftriaxone (1 gram) every 12 hours for maximum of 7 days

Intervention Type
Drug

Phase
Not Specified

Drug/device/biological/vaccine name(s)
ceftriaxone and sulbactam

Primary outcome measure
Clinical cure:
The criterion for the clinical cure requires total resolution of all signs and symptoms of the infection associated with complete healing of lesions (i.e. lesions disappear or are completely dry), or improvement of the above to such an extent that no further antimicrobial therapy is necessary, as assessed at the end of therapy. Clinical assessments will be carried out four times during the trial period: on admission into the study (Day 1), therapy assessment on Day 3 and Day 5, and end of therapy at Day 7.

The following sings and symptoms are examined during follow up visits for clinical response:
1. Fever
2. Chills
3. Malaise
4. Number of lesions
5. Length and width of largest lesion
6. Pain at the site of lesion
7. Ulceration of lesion
8. Type of discharge
9. Crust/scrub formation
10. Erythema around lesion
11. Warmth
12. Tenderness
13. Induration
14. Regional lymphadenopathy
15. New lesions

Secondary outcome measures
Bacteriological cure:
The secondary efficacy measure is microbiological outcome. To be considered microbiologically evaluable, patients should be clinically evaluable, have microbiological diagnosis based on isolation of a susceptible pathogen in the wound culture at study admission and should have end of therapy (Day 7) microbiological assessments. Microbiological outcome will be classified as follows:

Eradication: The absence of original pathogen(s) from post treatment wound culture performed at the end of therapy assessment.

Presumed Eradication: Presumed eradication of pathogen(s) isolated at study admission in the absence of a repeat wound culture due to inability to perform sampling at the end-of therapy assessment and definition of clinical cure/improvement is met.

Persistence: Lack of eradication of the original pathogen(s) isolated at the post treatment wound culture at the end of therapy assessments.

Presumed persistence: In a patient who is judged to be clinical failure, and wound culture is not possible or is not done, it is presumed that there is persistence of the pathogen.

Indeterminate: Wound culture was negative at study admission, or culture was not done at the end-of-therapy assessment even if the lesion has not healed at that assessment.

Super Infection: Isolation of a pathogen other than the original pathogen from post-treatment wound culture at the end-of therapy assessment.

Overall study start date
15/05/2007

Completion date
31/12/2007

Eligibility

Key inclusion criteria
1. Male and female patients aged >18 years
2. Diagnosis of skin and skin structure infections of sufficient severity and with signs of systemic illness requiring injectable antibiotics. The diagnosis of Skin and Soft Tissue Infections (SSTI) should be made on the basis of clinical and microbiological criteria as follows:
a. Infection that involves soft tissue (including deep and extensive cellulitis; abscesses, necrotizing fasciitis, surgical site infections; burns [<10% of total body surface area]) or
b. Requiring surgical interventions or
c. Associated with significant underlying disease/s such as diabetes mellitus, peripheral vascular disease, peripheral neuropathy or venous insufficiency.
A surgical intervention is not necessary for entering this study, but it will be allowed at the start of the study.
3. At least two of the following signs and symptoms:
3.1. Drainage or discharge
3.2. Fever (oral temperature >38.50 °C or 101.40 °F)
3.3. Erythema
3.4. Swelling / fluctuation
3.5. Local warmth
3.6. Pain / tenderness
3.7. White Blood Cell (WBC) count of >10.0000 cells / mm3
4. Patients of SSTI requiring parenteral antibiotic administration for minimum of 5 days
5. All patient should have a microbiological specimen (culture material) obtained from skin lesions prior initiation of therapy

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

400 completed cases will be evaluated (more participants may be recruited as some participants may not complete the intervenion / follow-up)

Key exclusion criteria
1. Unwilling or unable to give informed consent
2. Female patients of childbearing potential who are not practicing a reliable form of contraception
3. Significant mental retardation
4. Less than 18 years old
5. Hypersensitivity to ceftriaxone, sulbactam or any other beta-lactam agents
6. Presenting with sustained shock (Systolic Blood Pressure (SBP) <90 mm Hg for 2 hours, despite adequate fluid resuscitation)
7. Concomitant infection that requires treatment with another antimicrobial agent
8. Pseudomonas aeruginosa as a baseline isolate
9. Severely impaired arterial blood supply and insufficiency (absence of arterial pulse) such that the likelihood of amputation of the infected anatomical site is within one month
10. Presence of hepatic disease, acute hepatic failure or acute decompensation of chronic hepatic failure
11. Abnormal laboratory values at admission to study:
11.1. Serum Glutamic-Oxaloacetic Transaminase (SGOT), Serum Glutamic Pyruvic Transaminase (SGPT) >45 IU
11.2. Alkaline phosphate or serum bilirubin >2 mg/dl
11.3. Hemoglobin <9 g/dl, WBC<1000 /mm3
11.4. Platelet count < 75000 /mm3
12. Impaired renal function (serum creatinine >1.5 ml/min) or those requiring peritoneal dialysis or hemodialysis
13. Use of other antimicrobial drugs after wound specimen for culture has been obtained. Prior anti-infective use, (<3 days of oral antibiotics and <1 day any injectable antibiotics) even up to the day of patient enrollment, would be acceptable if a culture is obtained showing the persistence of pathogen.
14. Clinical laboratory determinations outside of an acceptable range should be excluded unless the finding can be attributed to current drug(s) therapy
15. Patients requiring further surgical intervention that might influence the evaluation of response to study medication
16. Any other underlying conditions compromising the ability to respond to a bacterial infection. e.g. AIDS, corticosteroid, chemotherapy, immunocompromised.
17. Any concomitant condition that, in the opinion of the investigator, would preclude an evaluation of a response or make it unlikely that the contemplated course of therapy could be completed
18. Any patient not reasonably expected to complete the trial

Date of first enrolment
15/05/2007

Date of final enrolment
31/12/2007

Locations

Countries of recruitment
India

Study participating centre
Maulana Azad Medical College and Hospital
New Delhi
India
100012

Sponsor information

Organisation
Ranbaxy Laboratories Ltd (India)

Sponsor details
Plot 90
Sect 32
Haryana
Gurgaon
India
122001
+91 124 4185741
Ganesh.Shetty@ranbaxy.com

Sponsor type
Industry

ROR
https://ror.org/030yyf771

Funder(s)

Funder type
Industry

Funder Name
Ranbaxy laboratories Ltd (India)

Results and Publications

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

Individual participant data (IPD) sharing plan
Not provided at time of registration

IPD sharing plan summary
Not provided at time of registration