ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: 11/09/2010

ClinicalTrials.gov ID: NCT00509106

Study Identification

Unique Protocol ID:	P903-09
Brief Title:	Comparative Study of Ceftaroline vs. Ceftriaxone in Adults With Community-Acquired Pneumonia (CAP)
Official Title:	A Phase 3, Multicenter, Randomized, Double-blind, Comparative Study to Evaluate the Safety and Efficacy of Ceftaroline Versus Ceftriaxone in the Treatment of Adult Subjects With Community-Acquired Pneumonia
Secondary IDs:	

Study Status

Record Verification:	November 2010
Overall Status:	Completed
Study Start:	July 2007
Primary Completion:	August 2008 [Actual]
Study Completion:	June 2009 [Actual]

Sponsor/Collaborators

Sponsor:	Forest Laboratories
Responsible Party:	
Collaborators:	

Oversight

FDA Regulated?:	Yes
Applicable Trial?:	Section 801 Clinical Trial? Yes

	Delayed Posting? No
IND/IDE Protocol?:	Yes
IND/IDE Information:	Grantor: CDER IND/IDE Number: 71,371 Serial Number: 092 Has Expanded Access? No
Review Board:	Approval Status: Approved Approval Number: 1048, 1523 Board Name: National Ethics Committee for Clinical Trials of Medicinal Products Board Affiliation: Academy of Medical Sciences National Ethics Committee for Clinical Trials of Medicinal Products Phone: 40.317.11.02 Email:
Data Monitoring?:	No
Plan to Share Data?:	
Oversight Authorities:	United States: Food and Drug Administration United States: Institutional Review Board Argentina: Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica Argentina: Human Research Bioethics Committee Chile: Comisión Nacional de Investigación Científica y Tecnológica Chile: Instituto de Salud Pública de Chile Peru: Ethics Committee Peru: General Directorate of Pharmaceuticals, Devices, and Drugs Peru: Ministry of Health Mexico: Ethics Committee Mexico: Ministry of Health Mexico: Federal Commission for Protection Against Health Risks Germany: Ethics Commission Germany: Federal Institute for Drugs and Medical Devices Poland: Office for Registration of Medicinal Products, Medical Devices and Biocidal Products Poland: Ministry of Health Austria: Agency for Health and Food Safety Austria: Ethikkommission Hungary: National Institute of Pharmacy Ukraine: Ministry of Health Ukraine: State Pharmacological Center - Ministry of Health Russia: Ethics Committee Russia: Ministry of Health of the Russian Federation Romania: National Medicines Agency Romania: State Institute for Drug Control Bulgaria: Bulgarian Drug Agency Bulgaria: Ministry of Health

Study Description

Brief Summary:	The purpose of the study is to determine if the antibiotic ceftaroline is safe and effective in the treatment of community-acquired pneumonia in adults.
Detailed Description:	Clinical trials is being held in different countries. The purpose of the study is to determine if the antibiotic ceftaroline is safe and effective in the treatment of community-acquired pneumonia in adults.

Conditions

Conditions:	Bacterial Pneumonia
Keywords:	ceftaroline Community-acquired pneumonia CAP Streptococcus pneumoniae Haemophilus influenzae Mycoplasma pneumoniae chlamydophila spp Legionella ssp multi-drug resistant Streptococcus pneumoniae (MDRSP) antimicrobial resistance pneumococci beta-lactam ceftaroline fosamil ceftriaxone antibiotic

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 3
Intervention Model:	Parallel Assignment
Number of Arms:	2
Masking:	Double Blind (Subject, Caregiver, Investigator, Outcomes Assessor)
Allocation:	Randomized
Endpoint Classification:	Safety/Efficacy Study
Enrollment:	622 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Ceftaroline fosamil for injection Ceftaroline fosamil was administered in two consecutive 300 mg IV infusions over 30 minutes, every 12 hours (q12h).	Drug: Ceftaroline fosamil for Injection 2 consecutive, 300 mg dose parenteral infused over 30 minutes, every 12 hours for 5 to 7 days Other Names: • Experimental
Active Comparator: IV Ceftriaxone Ceftriaxone was administered as a 1-g IV infusion over 30 minutes followed by IV saline placebo infused over 30 minutes, every 24 hours (q24h).	Drug: Ceftriaxone 1 g dose parenteral infused over 30 minutes over 30 minutes, every 24 hours for 5 to 7 days Other Names: • Active comparator Drug: Placebo Subjects randomized to receive ceftriaxone will receive ceftriaxone at a dose of 1 g infused over 30 minutes followed by IV saline placebo infused over 30 minutes, every 24 hours (q24h). Twelve hours after each dose of ceftriaxone and saline placebo (ie, between ceftriaxone doses), subjects in this group will receive two consecutive saline placebo infusions, each infused over 30 minutes q24h. The ceftriaxone and saline placebo infusions will correspond to the q12h infusions of ceftaroline, thereby maintaining the blind Other Names: • Placebo

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age:	18 Years
Maximum Age:	
Gender:	Both
Accepts Healthy Volunteers?:	No
Criteria:	Inclusion Criteria:
	Subjects with community-acquired pneumonia requiring:

- initial hospitalization or treatment in an emergency room or urgent care setting
- infection requiring initial treatment with IV antimicrobial

Exclusion Criteria:

- Community-acquired pneumonia suitable for outpatient therapy with an oral antimicrobial agent
- Respiratory tract infections not due to community-acquired bacterial pathogens
- Infections resistant to ceftriaxone
- Any condition requiring concomitant systemic corticosteroids
- History of any hypersensitivity or allergic reaction to any ß-lactam antimicrobial

Contacts/Locations

Study Officials: IM Hoepelman, MD
Study Principal Investigator
University Medical Center Utrecht

Locations: Romania
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References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Recruitment Details	Patients were recruited worldwide from July 2007 to August 2008
Pre-Assignment Details	Patients were screened for up to 24 hours

Reporting Groups

	Description
Ceftaroline Fosamil for Injection	Ceftaroline fosamil was administered in two consecutive 300 mg IV infusions over 30 minutes, every 12 hours (q12h).
IV Ceftriaxone	Ceftriaxone was administered as a 1-g IV infusion over 30 minutes followed by IV saline placebo infused over 30 minutes, every 24 hours (q24h).

Overall Study

	Ceftaroline Fosamil for Injection	IV Ceftriaxone
Started	315	307
Completed	284	278
Not Completed	31	29
Adverse Event	3	2
Noncompliance	0	1
At the request of sponsor/investigator	1	2
Withdrew consent	4	8
Lost to Follow-up	16	10
Other	1	0
Death	6	6

Baseline Characteristics

Reporting Groups

	Description
Ceftaroline Fosamil for Injection	Ceftaroline fosamil was administered in two consecutive 300 mg IV infusions over 30 minutes, every 12 hours (q12h).
IV Ceftriaxone	Ceftriaxone was administered as a 1-g IV infusion over 30 minutes followed by IV saline placebo infused over 30 minutes, every 24 hours (q24h).

Baseline Measures

	Ceftaroline Fosamil for Injection	IV Ceftriaxone	Total
Number of Participants	315	307	622

	Ceftaroline Fosamil for Injection	IV Ceftriaxone	Total
Age, Categorical [units: participants]			
<65 years	183	173	356
>=65 years	132	134	266
Age, Continuous [units: years] Mean (Standard Deviation)	59.0 (17.0)	60.0 (15.5)	59.5 (16.3)
Gender, Male/Female [units: participants]			
Female	126	105	231
Male	189	202	391

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Clinical Cure Rate for Ceftaroline Compared to That for Ceftriaxone at the Test of Cure (TOC) in the Modified Intent to Treat Efficacy (MITTE) Population
Measure Description	Cure:Total resolution of all signs and symptoms of pneumonia (ie,CABP), or improvement to such an extent that further antimicrobial therapy was not necessary Failure: Any of the following: • Persistence, incomplete clinical resolution, or worsening in signs and symptoms of CABP that required alternative antimicrobial therapy • Treatment-limiting AE leading to discontinuation of study drug therapy, when subject required alternative antimicrobial therapy to treat the pneumonia • Death wherein pneumonia (ie,CABP) was considered causative Indeterminate: Inability to determine an outcome
Time Frame	8-15 days after last dose of study drug
Safety Issue?	No

Analysis Population Description

The MITTE Population consisted of all subjects in the MITT Population (all randomized subjects who received any amount of the study drug) in PORT Risk Class III or IV. The Pneumonia Outcomes Research Team (PORT) scale of CAP severity in which Risk Class I is associated with the lowest risk for mortality and Risk Class V represents the highest risk.

Reporting Groups

	Description
Ceftaroline Fosamil for Injection	Ceftaroline fosamil was administered in two consecutive 300 mg IV infusions over 30 minutes, every 12 hours (q12h).
IV Ceftriaxone	Ceftriaxone was administered as a 1-g IV infusion over 30 minutes followed by IV saline placebo infused over 30 minutes, every 24 hours (q24h).

Measured Values

	Ceftaroline Fosamil for Injection	IV Ceftriaxone
Number of Participants Analyzed	315	307
Clinical Cure Rate for Ceftaroline Compared to That for Ceftriaxone at the Test of Cure (TOC) in the Modified Intent to Treat Efficacy (MITTE) Population [units: participants]		
Clinical cure	235	206
Clinical failure	47	56
Indeterminate	7	11

Statistical Analysis 1 for Clinical Cure Rate for Ceftaroline Compared to That for Ceftriaxone at the Test of Cure (TOC) in the Modified Intent to Treat Efficacy (MITTE) Population

Statistical Analysis Overview	Comparison Groups	Ceftaroline Fosamil for Injection, IV Ceftriaxone
	Comments	The primary objective of this study was to determine the noninferiority in the clinical cure rate for ceftaroline compared with that for ceftriaxone at TOC in the MITTE Population in adult subjects with CABP.
	Non-Inferiority or Equivalence Analysis?	Yes
	Comments	A two-sided 95% CI for the observed difference in the primary outcome measure (clinical cure rate)between the ceftaroline group and the ceftriaxone group was calculated based on the MITTE Population at the TOC visit. Noninferiority was concluded if the lower limit of the 95% CI was higher than –10% for the MITTE populations.

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	5.9
	Confidence Interval	(2-Sided) 95% -1.0 to 12.7

	Estimation Comments	isk difference corresponds to Ceftaroline clinical cure rate minus Ceftriaxone clinical cure rate. The confidence interval was calculated using the Miettinen and Nurminen method without adjustment.

2. Primary Outcome Measure:

Measure Title	Clinical Cure Rate for Ceftaroline Compared With That for Ceftriaxone at TOC in the Clinically Evaluable (CE) Population
Measure Description	
Time Frame	8-15 days after last dose of study drug
Safety Issue?	No

Outcome Measure Data Not Reported

3. Secondary Outcome Measure:

Measure Title	Clinical Response at End of Therapy (EOT)
Measure Description	
Time Frame	Last day of study drug administration
Safety Issue?	No

Outcome Measure Data Not Reported

4. Secondary Outcome Measure:

Measure Title	Microbiological Success Rate at TOC
Measure Description	
Time Frame	8-15 days after last dose of study drug
Safety Issue?	No

Outcome Measure Data Not Reported

5. Secondary Outcome Measure:

Measure Title	Overall Clinical and Radiographic Success Rate at TOC
Measure Description	
Time Frame	8-15 days after last dose of study drug
Safety Issue?	No

Outcome Measure Data Not Reported

6. Secondary Outcome Measure:

Measure Title	Clinical and Micriobiological Response by Pathogen at TOC
Measure Description	
Time Frame	8-15 days after last dose of study drug
Safety Issue?	No

Outcome Measure Data Not Reported

7. Secondary Outcome Measure:

Measure Title	Clinical Relapse at Late Follow Up (LFU) Visit
Measure Description	
Time Frame	21-35 days after last dose of study drug
Safety Issue?	No

Outcome Measure Data Not Reported

8. Secondary Outcome Measure:

Measure Title	Microbiological Reinfection/Recurrence at LFU
Measure Description	
Time Frame	21 to 35 days after last dose of study drug
Safety Issue?	No

Outcome Measure Data Not Reported

9. Secondary Outcome Measure:

Measure Title	Evaluate Safety
Measure Description	
Time Frame	first dose, throughout the treatment period, and up to the TOC visit
Safety Issue?	Yes

Outcome Measure Data Not Reported

Reported Adverse Events

Time Frame	[Not specified]
Additional Description	All safety analysis was performed on the Safety Population, those subjects that had received any amount of actual study drug

Reporting Groups

	Description
Ceftaroline Fosamil for Injection	Ceftaroline fosamil was administered in two consecutive 300 mg IV infusions over 30 minutes, every 12 hours (q12h).
IV Ceftriaxone	Ceftriaxone was administered as a 1-g IV infusion over 30 minutes followed by IV saline placebo infused over 30 minutes, every 24 hours (q24h).

Serious Adverse Events

	Ceftaroline Fosamil for Injection		IV Ceftriaxone	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Total	41/315 (13.02%)		39/307 (12.7%)	
Blood and lymphatic system disorders				
Disseminated intravascular coagulation [A] †	1/315 (0.32%)	1	0/307 (0%)	0
Cardiac disorders				
Acute myocardial infarction [A] †	0/315 (0%)	0	1/307 (0.33%)	1
Atrioventricular block complete [A] †	0/315 (0%)	0	1/307 (0.33%)	1
Cardiac arrest [A] †	1/315 (0.32%)	1	0/307 (0%)	0
Cardiac failure congestive [A] †	1/315 (0.32%)	1	0/307 (0%)	0
Cardio-respiratory arrest [A] †	0/315 (0%)	0	1/307 (0.33%)	1
Cardiopulmonary failure [A] †	1/315 (0.32%)	1	0/307 (0%)	0
Coronary artery disease [A] †	0/315 (0%)	0	1/307 (0.33%)	1
Myocardial infarction [A] †	0/315 (0%)	0	1/307 (0.33%)	1
Postinfarction angina [A] †	0/315 (0%)	0	1/307 (0.33%)	1

	Ceftaroline Fosamil for Injection		IV Ceftriaxone	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Endocrine disorders				
Hypothyroidism [A] †	1/315 (0.32%)	1	0/307 (0%)	0
Gastrointestinal disorders				
Duodenal ulcer [A] †	1/315 (0.32%)	1	0/307 (0%)	0
Gastric ulcer [A] †	0/315 (0%)	0	1/307 (0.33%)	1
Volvulus [A] †	0/315 (0%)	0	1/307 (0.33%)	1
Hepatobiliary disorders				
Hepatic failure [A] †	1/315 (0.32%)	1	0/307 (0%)	0
Infections and infestations				
Cellulitis [A] †	1/315 (0.32%)	1	0/307 (0%)	0
Endocarditis [A] †	0/315 (0%)	0	1/307 (0.33%)	1
Hepatitis C [A] †	0/315 (0%)	0	1/307 (0.33%)	1
Lung abscess [A] †	2/315 (0.63%)	2	3/307 (0.98%)	3
Lung infection pseudomonal [A] †	0/315 (0%)	0	1/307 (0.33%)	1
Pneumonia [A] †	7/315 (2.22%)	7	4/307 (1.3%)	4
Pyothorax [A] †	3/315 (0.95%)	3	0/307 (0%)	0
Sepsis [A] †	1/315 (0.32%)	1	1/307 (0.33%)	1
Septic shock [A] †	1/315 (0.32%)	1	0/307 (0%)	0
Staphylococcal bactgeraemia [A] †	0/315 (0%)	0	1/307 (0.33%)	1
Urinary tract infection [A] †	2/315 (0.63%)	2	1/307 (0.33%)	1
Investigations				
Hepatic enzyme increased [A] †	0/315 (0%)	0	1/307 (0.33%)	1
Metabolism and nutrition disorders				

	Ceftaroline Fosamil for Injection		IV Ceftriaxone	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Diabetes mellitus inadequate control [A] †	1/315 (0.32%)	1	0/307 (0%)	0
Hypoglycaemia [A] †	1/315 (0.32%)	1	0/307 (0%)	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Colon cancer [A] †	1/315 (0.32%)	1	0/307 (0%)	0
Lung neoplasm malignant [A] †	3/315 (0.95%)	3	0/307 (0%)	0
Malignant neoplasm progression [A] †	1/315 (0.32%)	1	0/307 (0%)	0
Metastatic neoplasm [A] †	1/315 (0.32%)	1	0/307 (0%)	0
Multiple myeloma [A] †	0/315 (0%)	0	1/307 (0.33%)	1
Prostate cancer [A] †	0/315 (0%)	0	1/307 (0.33%)	1
Renal neoplasm [A] †	1/315 (0.32%)	1	0/307 (0%)	0
Nervous system disorders				
Anoxic encephalopathy [A] †	1/315 (0.32%)	1	0/307 (0%)	0
Cerebrovascular accident [A] †	0/315 (0%)	0	1/307 (0.33%)	1
Convulsion [A] †	1/315 (0.32%)	1	0/307 (0%)	0
Hemiplegia [A] †	0/315 (0%)	0	1/307 (0.33%)	1
Toxic encephalopathy [A] †	1/315 (0.32%)	1	0/307 (0%)	0
Renal and urinary disorders				
Hydronephrosis [A] †	0/315 (0%)	0	1/307 (0.33%)	1
Renal failure [A] †	2/315 (0.63%)	2	0/307 (0%)	0
Reproductive system and breast disorders				
Epididymitis [A] †	0/315 (0%)	0	1/307 (0.33%)	1
Respiratory, thoracic and mediastinal disorders				
Acute pulmonary oedema [A] †	0/315 (0%)	0	1/307 (0.33%)	1

	Ceftaroline Fosamil for Injection		IV Ceftriaxone	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Acute respiratory failure [A] †	0/315 (0%)	0	1/307 (0.33%)	1
Asthma [A] †	0/315 (0%)	0	1/307 (0.33%)	1
Asthmatic crisis [A] †	0/315 (0%)	0	1/307 (0.33%)	1
Atelectasis [A] †	0/315 (0%)	0	1/307 (0.33%)	1
Chronic obstructive pulmonary disease [A] †	4/315 (1.27%)	4	5/307 (1.63%)	5
Interstitial lung disease [A] †	1/315 (0.32%)	1	0/307 (0%)	0
Pleural effusion [A] †	4/315 (1.27%)	4	5/307 (1.63%)	5
Pleurisy [A] †	1/315 (0.32%)	1	2/307 (0.65%)	2
Pulmonary embolism [A] †	4/315 (1.27%)	4	3/307 (0.98%)	3
Pulmonary oedema [A] †	2/315 (0.63%)	2	0/307 (0%)	0
Respiratory failure [A] †	2/315 (0.63%)	2	0/307 (0%)	0
Vascular disorders				
Cardiovascular insufficiency [A] †	1/315 (0.32%)	1	0/307 (0%)	0
Hypertensive crisis [A] †	0/315 (0%)	0	1/307 (0.33%)	1
Peripheral ischaemia [A] †	1/315 (0.32%)	1	0/307 (0%)	0

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (11.1)

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 2%

	Ceftaroline Fosamil for Injection		IV Ceftriaxone	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Total	67/315 (21.27%)		49/307 (15.96%)	
Gastrointestinal disorders				
Diarrhea [A] †	12/315 (3.81%)	12	9/307 (2.93%)	9

	Ceftaroline Fosamil for Injection		IV Ceftriaxone	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Nausea [A] †	6/315 (1.9%)	6	6/307 (1.95%)	6
Metabolism and nutrition disorders				
Hypokalemia [A] †	10/315 (3.17%)	10	5/307 (1.63%)	5
Nervous system disorders				
Headache [A] †	11/315 (3.49%)	11	5/307 (1.63%)	5
Psychiatric disorders				
Insomnia [A] †	10/315 (3.17%)	10	8/307 (2.61%)	8
Vascular disorders				
Hypertension [A] †	8/315 (2.54%)	8	8/307 (2.61%)	8
Phlebitis [A] †	10/315 (3.17%)	10	8/307 (2.61%)	8

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (11.1)

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There is NOT an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

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