ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: 09/20/2011

ClinicalTrials.gov ID: NCT00621504

Study Identification

Unique Protocol ID:	P903-08
Brief Title:	Comparative Study of Ceftaroline vs. Ceftriaxone in Adult Subjects 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, With Adjunctive Clarithromycin, in the Treatment of Adult Subjects With Community-Acquired Pneumonia
Secondary IDs:	

Study Status

Record Verification:	September 2011
Overall Status:	Completed
Study Start:	January 2008
Primary Completion:	December 2008 [Actual]
Study Completion:	June 2009 [Actual]

Sponsor/Collaborators

Sponsor:	Forest Laboratories
Responsible Party:	Sponsor
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: 062 Has Expanded Access? No
Review Board:	Approval Status: Approved Approval Number: 11/12/2007 Board Name: Copernicus Group IRB Board Affiliation: Copernicus Group IRB Phone: 919-465-4310 Email: irb@cgirb.com
Data Monitoring?:	No
Plan to Share Data?:	
Oversight Authorities:	United States: Food and Drug Administration United States: Institutional Review Board Hong Kong: Department of Health Hong Kong: Ethics Committee Hong Kong: Joint CUHK-NTEC Clinical Research Ethics Committee Malaysia: Ministry of Health Thailand: Ethical Committee Thailand: Food and Drug Administration Thailand: Khon Kaen University Ethics Committee for Human Research Thailand: Ministry of Public Health Argentina: Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica Argentina: Human Research Bioethics Committee Brazil: Ministry of Health Brazil: National Committee of Ethics in Research Brazil: National Health Surveillance Agency Russia: Ethics Committee Russia: Ministry of Health of the Russian Federation Russia: Pharmacological Committee, Ministry of Health Ukraine: Ministry of Health Ukraine: State Pharmacological Center - Ministry of Health Lithuania: Bioethics Committee Lithuania: State Medicine Control Agency - Ministry of Health Bulgaria: Bulgarian Drug Agency Bulgaria: Ministry of Health Romania: Ministry of Public Health Romania: National Medicines Agency

Study Description

Brief Summary:	The purpose of this study is to determine whether ceftaroline is effective and safe in the treatment of Community-Acquired Pneumonia
Detailed Description:	The purpose of this study is to determine whether ceftaroline is effective and safe in the treatment of Community-Acquired Pneumonia. Clinical trials for this study is held in many countries

Conditions

Conditions:	Bacterial Pneumonia
Keywords:	ceftaroline Community-acquired pneumonia CAP IV (intravenous) Streptococcus pneumoniae Haemophilus influenzae Mycoplasma pneumoniae Chlamydophila spp Legionella spp Multi-drug resistant Streptococcus pneumoniae (MDRSP) antimicrobial resistance pneumococci Ceftriaxone bacteria ß-lactam beta-lactam 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: 606 [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). In both treatment groups, two doses of oral clarithromycin (500 mg q12h), defined as adjunctive therapy, were initiated on Study Day 1 with study drug therapy in order to provide an immunomodulatory benefit and initial therapy for possible infection due to an atypical organism.	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: • Ceftaroline fosamil for injection Drug: Clarithromycin In both treatment groups, two doses of oral clarithromycin (500 mg q12h), defined as adjunctive therapy, were initiated on Study Day 1 with study drug therapy in order to provide an immunomodulatory benefit and initial therapy for possible infection due to an atypical organism. Other Names: • Clarithromycin
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). In both treatment groups, two doses of oral clarithromycin (500 mg q12h), defined as adjunctive therapy, were initiated on Study Day 1 with study drug therapy in order to provide an immunomodulatory benefit and initial therapy for possible infection due to an atypical organism.	Drug: IV Ceftriaxone 1 g dose parenteral infused over 30 minutes, every 24 hours, for 5 to 7 days Other Names: • Ceftriaxone 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 Drug: Clarithromycin In both treatment groups, two doses of oral clarithromycin (500 mg q12h), defined as adjunctive therapy, were initiated on Study Day 1 with study drug therapy in order to provide an immunomodulatory benefit and initial therapy for possible infection due to an atypical organism.

Arms	Assigned Interventions
	Other Names: • Clarithromycin

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age: 18 Years

Maximum Age:

Gender: Both

Accepts Healthy Volunteers?: No

Criteria: Inclusion Criteria:

Subjects are required to meet the following inclusion criteria:

- Community-acquired pneumonia
- initial hospitalization, or treatment in an emergency room or urgent care setting
- infection would require initial treatment with IV antimicrobials.

Exclusion Criteria:

Subjects must NOT meet any of the following exclusion criteria:

- CAP suitable for outpatient therapy with an oral antimicrobial agent
- respiratory tract infections not due to community-acquired bacterial
- Non-infectious causes of pulmonary infiltrates
- Pleural empyema
- Infection with an atypical organism
- History of any hypersensitivity or allergic reaction to any ß-lactam antimicrobial
- History of any hypersensitivity or allergic reaction to clarithromycin or any macrolide/ ketolide

Contacts/Locations

Study Officials: Thomas M File, MD, MS
Study Director
Summa Health System

Locations: Georgia
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References

Citations:

Links:

Study Data/Documents:

Study Results

Participant Flow

Recruitment Details	The enrollment period was from 02 January 2008 to 29 December 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	299	307
Completed	273	282
Not Completed	26	25
Adverse Event	1	3
At the request of sponsor/investigator	1	0
Withdrew consent	9	6
Lost to Follow-up	8	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	299	307	606
Age, Categorical [units: participants]			
<65 years	154	157	311
>= 65 years	145	150	295
Age, Continuous [units: years] Mean (Standard Deviation)	61.0 (16.6)	61.0 (16.6)	61.0 (16.6)
Gender, Male/Female [units: participants]			
Female	108	112	220
Male	191	195	386
Race/Ethnicity, Customized [units: participants]			
Hispanic	29	27	56
Non-Hispanic	270	280	550

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Clinical Cure Rate at Test-of-Cure (TOC) in the Modified Intent-to-Treat Efficacy (MITTE) Populations

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 to 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	291	300
Clinical Cure Rate at Test-of-Cure (TOC) in the Modified Intent-to-Treat Efficacy (MITTE) Populations [units: participants]		
Clinical Cure	244	233
Clinical Failure	34	58
Indeterminate	13	9

Statistical Analysis 1 for Clinical Cure Rate at Test-of-Cure (TOC) in the Modified Intent-to-Treat Efficacy (MITTE) Populations

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 to that for ceftriaxone at TOC in the CE and MITTE Populations 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 each of the CE and the MITTE Populations at the TOC visit. Noninferiority was concluded if the lower limit of the 95% CI was higher than –10% for each of the CE and MITTE Populations.

Method of Estimation	Estimation Parameter	Risk Difference (RD)
	Estimated Value	6.2
	Confidence Interval	(2-Sided) 95% -0.2 to 12.6
	Estimation Comments	Risk 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 to That for Ceftriaxone at Test-of-Cure (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 Test of Cure (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 Test of Cure (TOC)
Measure Description	
Time Frame	8-15 days after last day of study drug
Safety Issue?	No

Outcome Measure Data Not Reported

6. Secondary Outcome Measure:

Measure Title	Clinical and Microbiological 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)
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 Re-infection/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	Safety analysis was performed on the Safety Population, consisting of any subject who 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	28/298 (9.4%)		33/308 (10.71%)	
Blood and lymphatic system disorders				

	Ceftaroline Fosamil for Injection		IV Ceftriaxone	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Anemia [A] †	1/298 (0.34%)	1	0/308 (0%)	0
Lymphadenitis [A] †	1/298 (0.34%)	1	0/308 (0%)	0
Cardiac disorders				
Cardiac failure [A] †	1/298 (0.34%)	1	0/308 (0%)	0
Cardiac failure acute [A] †	0/298 (0%)	0	1/308 (0.32%)	1
Cardiac failure congestive [A] †	0/298 (0%)	0	1/308 (0.32%)	1
Cardio-respiratory arrest [A] †	0/298 (0%)	0	1/308 (0.32%)	1
Cardiomyopathy [A] †	0/298 (0%)	0	1/308 (0.32%)	1
Cardiopulmonary failure [A] †	0/298 (0%)	0	1/308 (0.32%)	1
Ischemic cardiomyopathy [A] †	1/298 (0.34%)	1	0/308 (0%)	0
Left ventricular failure [A] †	1/298 (0.34%)	1	0/308 (0%)	0
Myocardial infarction [A] †	0/298 (0%)	0	1/308 (0.32%)	1
Ventricular tachycardia [A] †	1/298 (0.34%)	1	0/308 (0%)	0
Gastrointestinal disorders				
Gastritis [A] †	1/298 (0.34%)	1	0/308 (0%)	0
Gastrointestinal perforation [A] †	1/298 (0.34%)	1	0/308 (0%)	0
General disorders				
Multiorgan disorder [A] †	0/298 (0%)	0	1/308 (0.32%)	1
Sudden death [A] †	2/298 (0.67%)	2	0/308 (0%)	0
Hepatobiliary disorders				
Acute hepatic failure [A] †	0/298 (0%)	0	1/308 (0.32%)	1
Cholecystitis acute [A] †	0/298 (0%)	0	2/308 (0.65%)	2
Hepatic failure [A] †	0/298 (0%)	0	1/308 (0.32%)	1

	Ceftaroline Fosamil for Injection		IV Ceftriaxone	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Immune system disorders				
Hypersensitivity [A] †	0/298 (0%)	0	1/308 (0.32%)	1
Infections and infestations				
Bronchitis [A] †	1/298 (0.34%)	1	0/308 (0%)	0
Cellulitis [A] †	0/298 (0%)	0	1/308 (0.32%)	1
Empyema [A] †	1/298 (0.34%)	1	2/308 (0.65%)	2
Endocarditis [A] †	0/298 (0%)	0	1/308 (0.32%)	1
Gastroenteritis [A] †	0/298 (0%)	0	2/308 (0.65%)	2
Lung abscess [A] †	0/298 (0%)	0	1/308 (0.32%)	1
Pneumonia [A] †	2/298 (0.67%)	2	5/308 (1.62%)	5
Pulmonary tuberculosis [A] †	0/298 (0%)	0	1/308 (0.32%)	1
Pyothorax [A] †	1/298 (0.34%)	1	0/308 (0%)	0
Sepsis [A] †	1/298 (0.34%)	1	0/308 (0%)	0
Tuberculosis [A] †	1/298 (0.34%)	1	0/308 (0%)	0
Urosepsis [A] †	0/298 (0%)	0	1/308 (0.32%)	1
Investigations				
Liver function test abnormal [A] †	1/298 (0.34%)	1	0/308 (0%)	0
Metabolism and nutrition disorders				
Diabetes mellitus [A] †	1/298 (0.34%)	1	1/308 (0.32%)	1
Gout [A] †	0/298 (0%)	0	1/308 (0.32%)	1
Type 1 diabetes mellitus [A] †	0/298 (0%)	0	1/308 (0.32%)	1
Type 2 diabetes mellitus [A] †	0/298 (0%)	0	1/308 (0.32%)	1
Musculoskeletal and connective tissue disorders				

	Ceftaroline Fosamil for Injection		IV Ceftriaxone	
	Affected/At Risk (%)	# Events	Affected/At Risk (%)	# Events
Myopathy [A] †	0/298 (0%)	0	1/308 (0.32%)	1
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Lung adenocarcinoma [A] †	1/298 (0.34%)	1	0/308 (0%)	0
Lung adenocarcinoma metastatic [A] †	0/298 (0%)	0	1/308 (0.32%)	1
Lung neoplasm [A] †	1/298 (0.34%)	1	0/308 (0%)	0
Metastases to liver [A] †	1/298 (0.34%)	1	0/308 (0%)	0
Pancreatic neoplasm [A] †	1/298 (0.34%)	1	0/308 (0%)	0
Small cell lung cancer, state unspecified [A] †	1/298 (0.34%)	1	0/308 (0%)	0
Nervous system disorders				
Thrombotic stroke [A] †	1/298 (0.34%)	1	0/308 (0%)	0
Renal and urinary disorders				
Urinary retention [A] †	0/298 (0%)	0	1/308 (0.32%)	1
Respiratory, thoracic and mediastinal disorders				
Asthma [A] †	0/298 (0%)	0	2/308 (0.65%)	2
Chronic obstructive pulmonary disease [A] †	0/298 (0%)	0	1/308 (0.32%)	1
Pleural effusion [A] †	1/298 (0.34%)	1	1/308 (0.32%)	1
Pulmonary embolism [A] †	1/298 (0.34%)	1	1/308 (0.32%)	1
Respiratory failure [A] †	2/298 (0.67%)	2	1/308 (0.32%)	1
Vascular disorders				
Aortic aneurysm [A] †	1/298 (0.34%)	1	0/308 (0%)	0
Aortic dissection [A] †	1/298 (0.34%)	1	0/308 (0%)	0
Deep vein thrombosis [A] †	0/298 (0%)	0	1/308 (0.32%)	1

† 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	65/298 (21.81%)		53/308 (17.21%)	
Gastrointestinal disorders				
Constipation [A] †	7/298 (2.35%)	7	5/308 (1.62%)	5
Diarrhea [A] †	14/298 (4.7%)	14	7/308 (2.27%)	7
Nausea [A] †	8/298 (2.68%)	8	8/308 (2.6%)	8
Metabolism and nutrition disorders				
Hypokalemia [A] †	4/298 (1.34%)	4	10/308 (3.25%)	10
Nervous system disorders				
Headache [A] †	10/298 (3.36%)	10	4/308 (1.3%)	4
Psychiatric disorders				
Insomnia [A] †	9/298 (3.02%)	9	6/308 (1.95%)	6
Vascular disorders				
Hypertension [A] †	6/298 (2.01%)	6	8/308 (2.6%)	8
Phlebitis [A] †	7/298 (2.35%)	7	5/308 (1.62%)	5

† 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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