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Trial record **1 of 1** for: CR012931

Previous Study | Return to List | Next Study

An Effectiveness, Safety, and Microbiology Study of Doripenem in Patients With Nosocomial (Hospital-acquired) Pneumonia

This study has been completed.

Sponsor:
PriCara, Unit of Ortho-McNeil, Inc.

Information provided by (Responsible Party):
PriCara, Unit of Ortho-McNeil, Inc.

ClinicalTrials.gov Identifier:
NCT00502801

First received: July 16, 2007
Last updated: September 19, 2013
Last verified: September 2013
History of Changes

Full Text View | Tabular View | Study Results | Disclaimer | How to Read a Study Record

Results First Received: February 13, 2013

Study Type:	Interventional
Study Design:	Endpoint Classification: Safety/Efficacy Study; Intervention Model: Single Group Assignment; Masking: Open Label; Primary Purpose: Treatment
Conditions:	Pneumonia Bacterial Pneumonia Ventilator-Associated Pneumonia Infections, Nosocomial
Intervention:	Drug: doripenem

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
No text entered.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
Two enrolled subjects didn't take study medication and weren't qualified for safety population.

Reporting Groups

	Description
Doripenem	1g i.v. infused over 4 hours every 8 hours from day 1 to day 8 to 14, depending on length of treatment

Participant Flow for 2 periods

Period 1: Treatment Period

	Doripenem
STARTED	183
COMPLETED	129

NOT COMPLETED	54
Withdrawal by Subject	3
Adverse Event	7
Death	14
OTHER	30

Period 2: End of Therapy to Test of Cure

	Doripenem
STARTED	129
COMPLETED	121
NOT COMPLETED	8
Withdrawal by Subject	1
Lost to Follow-up	2
Death	3
OTHER	2

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
Doripenem	1g i.v. infused over 4 hours every 8 hours from day 1 to day 8 to 14, depending on length of treatment

Baseline Measures

	Doripenem
Number of Participants [units: participants]	183
Age [units: years] Mean (Standard Deviation)	56 (20.23)
Gender [units: participants]	
Female	71
Male	112
Region of Enrollment [units: participants]	
ARGENTINA	4
CANADA	6
CHILE	9
CROATIA	21
FRANCE	6

INDIA	10
RUSSIA	2
UKRAINE	5
USA	120
race [units: participants]	
AMERICAN INDIAN OR ALASKA	2
ASIAN	14
BLACK OR AFRICAN AMERICAN	14
OTHER, SPECIFY	2
WHITE	151
ethnicity [units: participants]	
HISPANIC OR LATINO	20
NOT HISPANIC OR LATINO	158
OTHER	5
BMI [units: kg/m^2] Mean (Standard Deviation)	27.4 (8.63)

Outcome Measures

Hide All Outcome Measures

1. Primary: Clinical Response Rates and 95% Confidence Intervals at the Test-of-Cure Assessment. [Time Frame: 5 to 21 days after the last dose of study therapy, or at early termination.]

Measure Type	Primary
Measure Title	Clinical Response Rates and 95% Confidence Intervals at the Test-of-Cure Assessment.
Measure Description	The table below shows the percentage of subjects who had a clinical response of “clinical cure” at the Late Follow-up Visit as assigned by the medical monitor. A clinical response of “clinical cure” is defined as no further antibacterial therapy needed for treatment of the infection.
Time Frame	5 to 21 days after the last dose of study therapy, or at early termination.
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Clinically Evaluable: Subset of the ITT population who received at least 5 days of study medication unless deemed a clinical failure with at least 2 full days of therapy, and excluding those subjects with a clinical outcome of Not Evaluable at the TOC assessment.

Reporting Groups

	Description
Doripenem	1g i.v. infused over 4 hours every 8 hours from day 1 to day 8 to 14, depending on length of treatment

Measured Values

	Doripenem
	122

Number of Participants Analyzed [units: participants]	
Clinical Response Rates and 95% Confidence Intervals at the Test-of-Cure Assessment. [units: Percentage of participants] Number (95% Confidence Interval)	
All Clinically Evaluable Subjects	**63.9 (54.7 to 72.4)**
Subjects with Nosocomial Pneumonia	**66.0 (51.7 to 78.5)**
Subjects with Ventilator Associated Pneumonia	**64.4 (50.9 to 76.4)**
Subjects with Healthcare Associated Pneumonia	**50.0 (18.7 to 81.3)**

No statistical analysis provided for Clinical Response Rates and 95% Confidence Intervals at the Test-of-Cure Assessment.

2. Secondary: Clinical Response Rates at the Late Follow-up Assessment. [Time Frame: 28 to 35 days after last dose of study therapy]

Measure Type	Secondary
Measure Title	Clinical Response Rates at the Late Follow-up Assessment.
Measure Description	The table below shows the percentage of subjects who had a clinical response of “clinical cure” at the Late Follow-up Visit as assigned by the medical monitor. A clinical response of "clinical cure" is defined as no further antibacterial therapy needed for treatment of the infection.
Time Frame	28 to 35 days after last dose of study therapy
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Clinically Evaluable: Subset of the ITT population who received at least 5 days of study medication unless deemed a clinical failure with at least 2 full days of therapy, and excluding those subjects with a clinical outcome of Not Evaluable at the TOC assessment.

Reporting Groups

	Description
Doripenem	1g i.v. infused over 4 hours every 8 hours from day 1 to day 8 to 14, depending on length of treatment

Measured Values

	Doripenem
Number of Participants Analyzed [units: participants]	**78**
Clinical Response Rates at the Late Follow-up Assessment. [units: Percentage of participants]	
All Clinically Evaluable Subjects	**83.3**
Subjects with Nosocomial Pneumonia	**82.9**
Subjects with Ventilator Associated Pneumonia	**84.2**
Subjects with Healthcare Associated Pneumonia	**80.0**

No statistical analysis provided for Clinical Response Rates at the Late Follow-up Assessment.

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Reporting Groups

	Description
Doripenem	1g i.v. infused over 4 hours every 8 hours from day 1 to day 8 to 14, depending on length of treatment

Serious Adverse Events

	Doripenem
Total, serious adverse events	
# participants affected / at risk	**70/183 (38.25%)**
Blood and lymphatic system disorders	
Neutropenia [*1]	
# participants affected / at risk	**1/183 (0.55%)**
Cardiac disorders	
Bradycardia [*1]	
# participants affected / at risk	**1/183 (0.55%)**
Cardiac Arrest [*1]	
# participants affected / at risk	**6/183 (3.28%)**
Cardiac Failure Congestive [*1]	
# participants affected / at risk	**2/183 (1.09%)**
Cardio-Respiratory Arrest [*1]	
# participants affected / at risk	**6/183 (3.28%)**
Cardiopulmonary Failure [*1]	
# participants affected / at risk	**1/183 (0.55%)**
Myocardial Infarction [*1]	
# participants affected / at risk	**1/183 (0.55%)**
Pericardial Effusion [*1]	
# participants affected / at risk	**1/183 (0.55%)**
Ventricular Fibrillation [*1]	
# participants affected / at risk	**1/183 (0.55%)**
Congenital, familial and genetic disorders	
Sickle Cell Anaemia [*1]	
# participants affected / at risk	**1/183 (0.55%)**
Spondylolisthesis [*1]	
# participants affected / at risk	**1/183 (0.55%)**
Gastrointestinal disorders	
Gastric Ulcer [*1]	
# participants affected / at risk	**1/183 (0.55%)**
Gastrointestinal Haemorrhage [*1]	
# participants affected / at risk	**1/183 (0.55%)**

Impaired Gastric Emptying [*1]	
# participants affected / at risk	1/183 (0.55%)
Localised Intraabdominal Fluid Collection [*1]	
# participants affected / at risk	1/183 (0.55%)
Pancreatic Fistula [*1]	
# participants affected / at risk	1/183 (0.55%)
General disorders	
Multi-Organ Failure [*1]	
# participants affected / at risk	1/183 (0.55%)
Ulcer [*1]	
# participants affected / at risk	1/183 (0.55%)
Infections and infestations	
Bacteraemia [*1]	
# participants affected / at risk	1/183 (0.55%)
Candidiasis [*1]	
# participants affected / at risk	1/183 (0.55%)
Empyema [*1]	
# participants affected / at risk	1/183 (0.55%)
Lung Infection Pseudomonal [*1]	
# participants affected / at risk	1/183 (0.55%)
Meningitis Bacterial [*1]	
# participants affected / at risk	1/183 (0.55%)
Meningoencephalitis Herpetic [*1]	
# participants affected / at risk	1/183 (0.55%)
Pneumonia [*1]	
# participants affected / at risk	9/183 (4.92%)
Postoperative Wound Infection [*1]	
# participants affected / at risk	1/183 (0.55%)
Pyelonephritis [*1]	
# participants affected / at risk	1/183 (0.55%)
Renal Abscess [*1]	
# participants affected / at risk	1/183 (0.55%)
Retroperitoneal Abscess [*1]	
# participants affected / at risk	1/183 (0.55%)
Sepsis [*1]	
# participants affected / at risk	4/183 (2.19%)
Septic Shock [*1]	
# participants affected / at risk	1/183 (0.55%)
Sinusitis [*1]	
# participants affected / at risk	1/183 (0.55%)
Wound Infection [*1]	
# participants affected / at risk	1/183 (0.55%)
Injury, poisoning and procedural complications	
Feeding Tube Complication [*1]	
# participants affected / at risk	1/183 (0.55%)

Head Injury [*1]	
# participants affected / at risk	1/183 (0.55%)
Subdural Haematoma [*1]	
# participants affected / at risk	1/183 (0.55%)
Traumatic Brain Injury [*1]	
# participants affected / at risk	2/183 (1.09%)
Weaning Failure [*1]	
# participants affected / at risk	1/183 (0.55%)
Investigations	
White Blood Cell Count Increased [*1]	
# participants affected / at risk	1/183 (0.55%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)	
Bile Duct Cancer [*1]	
# participants affected / at risk	1/183 (0.55%)
Gastric Cancer [*1]	
# participants affected / at risk	1/183 (0.55%)
Nervous system disorders	
Anoxic Encephalopathy [*1]	
# participants affected / at risk	1/183 (0.55%)
Cerebral Ischaemia [*1]	
# participants affected / at risk	1/183 (0.55%)
Coma [*1]	
# participants affected / at risk	1/183 (0.55%)
Convulsion [*1]	
# participants affected / at risk	1/183 (0.55%)
Psychomotor Hyperactivity [*1]	
# participants affected / at risk	1/183 (0.55%)
Renal and urinary disorders	
Haematuria [*1]	
# participants affected / at risk	1/183 (0.55%)
Obstructive Uropathy [*1]	
# participants affected / at risk	1/183 (0.55%)
Renal Failure [*1]	
# participants affected / at risk	2/183 (1.09%)
Renal Failure Acute [*1]	
# participants affected / at risk	1/183 (0.55%)
Respiratory, thoracic and mediastinal disorders	
Acute Respiratory Distress Syndrome [*1]	
# participants affected / at risk	4/183 (2.19%)
Acute Respiratory Failure [*1]	
# participants affected / at risk	1/183 (0.55%)
Atelectasis [*1]	
# participants affected / at risk	1/183 (0.55%)
Chronic Obstructive Pulmonary Disease [*1]	
# participants affected / at risk	1/183 (0.55%)

Hydropneumothorax [*1]	
# participants affected / at risk	**1/183 (0.55%)**
Hypoxia [*1]	
# participants affected / at risk	**2/183 (1.09%)**
Pleural Effusion [*1]	
# participants affected / at risk	**3/183 (1.64%)**
Pneumonia Aspiration [*1]	
# participants affected / at risk	**3/183 (1.64%)**
Pulmonary Oedema [*1]	
# participants affected / at risk	**1/183 (0.55%)**
Respiratory Arrest [*1]	
# participants affected / at risk	**4/183 (2.19%)**
Respiratory Distress [*1]	
# participants affected / at risk	**2/183 (1.09%)**
Respiratory Failure [*1]	
# participants affected / at risk	**9/183 (4.92%)**
Skin and subcutaneous tissue disorders	
Rash Papular [*1]	
# participants affected / at risk	**1/183 (0.55%)**
Vascular disorders	
Air Embolism [*1]	
# participants affected / at risk	**1/183 (0.55%)**
Haematoma [*1]	
# participants affected / at risk	**1/183 (0.55%)**
Haemorrhage [*1]	
# participants affected / at risk	**1/183 (0.55%)**
Hypertension [*1]	
# participants affected / at risk	**1/183 (0.55%)**
Hypotension [*1]	
# participants affected / at risk	**2/183 (1.09%)**

* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRA Version 10.1

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Doripenem	1g i.v. infused over 4 hours every 8 hours from day 1 to day 8 to 14, depending on length of treatment

Other Adverse Events

	Doripenem
Total, other (not including serious) adverse events	
# participants affected / at risk	**93/183 (50.82%)**
Blood and lymphatic system disorders	
Anaemia *1	
# participants affected / at risk	**16/183 (8.74%)**
Thrombocythaemia *1	
# participants affected / at risk	**11/183 (6.01%)**
Gastrointestinal disorders	
Constipation *1	
# participants affected / at risk	**14/183 (7.65%)**
Diarrhoea *1	
# participants affected / at risk	**22/183 (12.02%)**
Nausea *1	
# participants affected / at risk	**14/183 (7.65%)**
Vomiting *1	
# participants affected / at risk	**10/183 (5.46%)**
General disorders	
Pyrexia *1	
# participants affected / at risk	**12/183 (6.56%)**
Infections and infestations	
Fungal Infection *1	
# participants affected / at risk	**17/183 (9.29%)**
Urinary Tract Infection *1	
# participants affected / at risk	**12/183 (6.56%)**
Metabolism and nutrition disorders	
Hypoglycaemia *1	
# participants affected / at risk	**10/183 (5.46%)**
Hypokalaemia *1	
# participants affected / at risk	**21/183 (11.48%)**
Vascular disorders	
Hypertension *1	
# participants affected / at risk	**13/183 (7.10%)**

* Events were collected by non-systematic assessment
1 Term from vocabulary, MedDRA Version 10.1

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.
There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.
The agreement is: ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. ☑ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days**. The sponsor cannot require changes to the communication and cannot extend the embargo. ☐ Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

Results Point of Contact:

Name/Title: Vice President, Data Generation
Organization: Janssen Scientific Affairs, LLC
phone: 908 927-2943

No publications provided

Responsible Party:	PriCara, Unit of Ortho-McNeil, Inc.
ClinicalTrials.gov Identifier:	NCT00502801 History of Changes
Other Study ID Numbers:	**CR012931**, DORIINI2002
Study First Received:	July 16, 2007
Results First Received:	February 13, 2013
Last Updated:	September 19, 2013
Health Authority:	United States: Food and Drug Administration

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