Trial record **1 of 1** for: CR012934
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A Safety and Tolerability Study of Doripenem in Patients With Abdominal Infections or Pneumonia

This study has been completed.

Sponsor:
Johnson & Johnson Pharmaceutical Research & Development, L.L.C.

Information provided by:
Johnson & Johnson Pharmaceutical Research & Development, L.L.C.

ClinicalTrials.gov Identifier:
NCT00515034

First received: August 10, 2007
Last updated: May 9, 2011
Last verified: May 2011
History of Changes

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

Results First Received: November 13, 2009

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Conditions:	Pneumonia, Ventilator-Associated Pneumonia, Bacterial Pneumonia Abdominal Abscess Bacterial Infections
Interventions:	Drug: Imipenem/cilastatin 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
No text entered.

Reporting Groups

	Description
VAP Treated With Doripenem	Doripenem 1 g infused over 4 hours at 8-hour intervals for patients with Ventilator-Associated Pneumonia (VAP) for 7-14 days
VAP Treated With Imipenem/Cilastatin	Imipenem/cilastatin 1 g infused over 1 hour at 8-hour intervals for patients with Ventilator-Associated Pneumonia (VAP)for 7-14 days
cIAI Treated With Doripenem	Doripenem 1 g infused over 4 hours at 8-hour intervals for patients with complicated Intra-Abdominal Infection (cIAI) for 5-14 days
cIAI Treated With Imipenem/Cilastatin	

	Imipenem/cilastatin 1 g infused over 1 hour at 8-hour intervals for patients with complicated Intra-Abdominal Infection (cIAI) for 5-14 days

Participant Flow: Overall Study

	VAP Treated With Doripenem	VAP Treated With Imipenem/Cilastatin	cIAI Treated With Doripenem	cIAI Treated With Imipenem/Cilastatin
STARTED	49	15	62	20
TREATED	48	15	61	19
COMPLETED	41	13	54	15
NOT COMPLETED	8	2	8	5
Adverse Event	2	0	1	0
Death	4	2	1	3
Withdrawal by Subject	1	0	3	0
Physician Decision	0	0	1	1
unknown	1	0	2	1

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
VAP Treated With Doripenem	Doripenem 1 g infused over 4 hours at 8-hour intervals for patients with Ventilator-Associated Pneumonia (VAP) for 7-14 days
VAP Treated With Imipenem/Cilastatin	Imipenem/cilastatin 1 g infused over 1 hour at 8-hour intervals for patients with Ventilator-Associated Pneumonia (VAP)for 7-14 days
cIAI Treated With Doripenem	Doripenem 1 g infused over 4 hours at 8-hour intervals for patients with complicated Intra-Abdominal Infection (cIAI) for 5-14 days
cIAI Treated With Imipenem/Cilastatin	Imipenem/cilastatin 1 g infused over 1 hour at 8-hour intervals for patients with complicated Intra-Abdominal Infection (cIAI) for 5-14 days
Total	Total of all reporting groups

Baseline Measures

	VAP Treated With Doripenem	VAP Treated With Imipenem/Cilastatin	cIAI Treated With Doripenem	cIAI Treated With Imipenem/Cilastatin	Total
Number of Participants [units: participants]	49	15	62	20	146
Age, Customized [units: participants]					
<65 years	35	11	48	16	110
>=65 years	14	4	14	4	36

Gender [units: participants]					
Female	**12**	**6**	**25**	**5**	**48**
Male	**37**	**9**	**37**	**15**	**98**
Region of Enrollment [units: participants]					
North America	**14**	**3**	**24**	**7**	**48**
Europe	**19**	**7**	**15**	**4**	**45**
South America	**16**	**5**	**23**	**9**	**53**

Outcome Measures

Hide All Outcome Measures

1. Primary: Patients With Incidence of Treatment-emergent Adverse Events (TEAEs). [Time Frame: from the initiation of the first infusion of study drug therapy and up to 30 days after the completion of study drug therapy]

Measure Type	Primary
Measure Title	Patients With Incidence of Treatment-emergent Adverse Events (TEAEs).
Measure Description	Treatment-emergent adverse events (TEAEs) are defined as AEs with onset dates on or after the date of the start of the infusion of first dose of study therapy and within 30 days after administration of the last dose of study therapy.
Time Frame	from the initiation of the first infusion of study drug therapy and up to 30 days after the completion of study drug therapy
Safety Issue	Yes

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.
population is the as-treated analysis set - that is subjects who were administered therapy

Reporting Groups

	Description
VAP Treated With Doripenem	Doripenem 1 g infused over 4 hours at 8-hour intervals for patients with Ventilator-Associated Pneumonia (VAP) for 7-14 days
VAP Treated With Imipenem/Cilastatin	Imipenem/cilastatin 1 g infused over 1 hour at 8-hour intervals for patients with Ventilator-Associated Pneumonia (VAP)for 7-14 days
cIAI Treated With Doripenem	Doripenem 1 g infused over 4 hours at 8-hour intervals for patients with complicated Intra-Abdominal Infection (cIAI) for 5-14 days
cIAI Treated With Imipenem/Cilastatin	Imipenem/cilastatin 1 g infused over 1 hour at 8-hour intervals for patients with complicated Intra-Abdominal Infection (cIAI) for 5-14 days

Measured Values

	VAP Treated With Doripenem	**VAP Treated With Imipenem/Cilastatin**	**cIAI Treated With Doripenem**	**cIAI Treated With Imipenem/Cilastatin**
Number of Participants Analyzed [units: participants]	**48**	**15**	**61**	**19**
Patients With Incidence of Treatment-emergent Adverse Events (TEAEs). [units: participants]	**42**	**13**	**37**	**15**

No statistical analysis provided for Patients With Incidence of Treatment-emergent Adverse Events (TEAEs).

2. Secondary: Patients With VAP Who Were Clinically Cured [Time Frame: 7 to 14 days after the end of IV therapy]

Measure Type	Secondary
Measure Title	Patients With VAP Who Were Clinically Cured
Measure Description	clinical cure is the complete resolution of signs and symptoms of pneumonia or lack of progression of chest x-ray abnormalities to such an extent that no further antimicrobial therapy was necessary.
Time Frame	7 to 14 days after the end of IV 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.
the population is the number of participants who are clinically evaluable

Reporting Groups

	Description
VAP Treated With Doripenem	Doripenem 1 g infused over 4 hours at 8-hour intervals for patients with Ventilator-Associated Pneumonia (VAP) for 7-14 days
VAP Treated With Imipenem/Cilastatin	Imipenem/cilastatin 1 g infused over 1 hour at 8-hour intervals for patients with Ventilator-Associated Pneumonia (VAP)for 7-14 days
cIAI Treated With Doripenem	Doripenem 1 g infused over 4 hours at 8-hour intervals for patients with complicated Intra-Abdominal Infection (cIAI) for 5-14 days
cIAI Treated With Imipenem/Cilastatin	Imipenem/cilastatin 1 g infused over 1 hour at 8-hour intervals for patients with complicated Intra-Abdominal Infection (cIAI) for 5-14 days

Measured Values

	VAP Treated With Doripenem	**VAP Treated With Imipenem/Cilastatin**	**cIAI Treated With Doripenem**	**cIAI Treated With Imipenem/Cilastatin**
Number of Participants Analyzed [units: participants]	**25**	**9**	**0**	**0**
Patients With VAP Who Were Clinically Cured [units: participants]	**16**	**7**		

Statistical Analysis 1 for Patients With VAP Who Were Clinically Cured

Groups [1]	VAP Treated With Doripenem vs. VAP Treated With Imipenem/Cilastatin
Non-Inferiority/Equivalence Test [2]	Yes
Method [3]	normal approximation to the binomial
Risk Difference (RD) [4]	-13.8
95% Confidence Interval	-54.4 to 26.8

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	There is no formal hypothesis test for this outcome. Only summary data are provided.

[2]	Details of power calculation, definition of non-inferiority margin, and other key parameters:
	Percent of participants who are clinically cured including 95% confidence intervals are provided.
[3]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[4]	Other relevant estimation information:
	Treatment difference (doripenem minus imipenem/cilastatin) in percent of participants who are clinically cured.

3. Secondary: Patients With cIAI Who Were Clinically Cured [Time Frame: 7 to 14 days after the end of IV therapy]

Measure Type	Secondary
Measure Title	Patients With cIAI Who Were Clinically Cured
Measure Description	clinical cure is the complete resolution or significant improvement of signs or symptoms of cIAI, such that no additional antimicrobial therapy or surgical or percutaneous intervention is required for the treatment of the current infection.
Time Frame	7 to 14 days after the end of IV 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.
participants who were clinically evaluable

Reporting Groups

	Description
VAP Treated With Doripenem	Doripenem 1 g infused over 4 hours at 8-hour intervals for patients with Ventilator-Associated Pneumonia (VAP) for 7-14 days
VAP Treated With Imipenem/Cilastatin	Imipenem/cilastatin 1 g infused over 1 hour at 8-hour intervals for patients with Ventilator-Associated Pneumonia (VAP)for 7-14 days
cIAI Treated With Doripenem	Doripenem 1 g infused over 4 hours at 8-hour intervals for patients with complicated Intra-Abdominal Infection (cIAI) for 5-14 days
cIAI Treated With Imipenem/Cilastatin	Imipenem/cilastatin 1 g infused over 1 hour at 8-hour intervals for patients with complicated Intra-Abdominal Infection (cIAI) for 5-14 days

Measured Values

	VAP Treated With Doripenem	**VAP Treated With Imipenem/Cilastatin**	**cIAI Treated With Doripenem**	**cIAI Treated With Imipenem/Cilastatin**
Number of Participants Analyzed [units: participants]	**0**	**0**	**47**	**14**
Patients With cIAI Who Were Clinically Cured [units: participants]			**39**	**9**

Statistical Analysis 1 for Patients With cIAI Who Were Clinically Cured

Groups [1]	cIAI Treated With Doripenem vs. cIAI Treated With Imipenem/Cilastatin
Non-Inferiority/Equivalence Test [2]	Yes
Method [3]	normal approximation to binomial

Risk Difference (RD) [4]	18.7
95% Confidence Interval	-13.2 to 50.6

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	There is no formal hypothesis test for this outcome. Only summary data are presented.
[2]	Details of power calculation, definition of non-inferiority margin, and other key parameters:
	Percent of participants who are clinically cured including 95% confidence intervals are provided.
[3]	Other relevant method information, such as adjustments or degrees of freedom:
	No text entered.
[4]	Other relevant estimation information:
	Treatment difference (doripenem minus imipenem) in percent of participants who are clinically cured.

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	All adverse events were reported from the time a signed and dated informed consent form was obtained until 30 days after the completion of study drug therapy
Additional Description	No text entered.

Reporting Groups

	Description
VAP Treated With Doripenem	Doripenem 1 g infused over 4 hours at 8-hour intervals for patients with Ventilator-Associated Pneumonia (VAP) for 7-14 days
VAP Treated With Imipenem/Cilastatin	Imipenem/cilastatin 1 g infused over 1 hour at 8-hour intervals for patients with Ventilator-Associated Pneumonia (VAP)for 7-14 days
cIAI Treated With Doripenem	Doripenem 1 g infused over 4 hours at 8-hour intervals for patients with complicated Intra-Abdominal Infection (cIAI) for 5-14 days
cIAI Treated With Imipenem/Cilastatin	Imipenem/cilastatin 1 g infused over 1 hour at 8-hour intervals for patients with complicated Intra-Abdominal Infection (cIAI) for 5-14 days

Serious Adverse Events

	VAP Treated With Doripenem	**VAP Treated With Imipenem/Cilastatin**	**cIAI Treated With Doripenem**	**cIAI Treated With Imipenem/Cilastatin**
Total, serious adverse events				
# participants affected / at risk	**16/48 (33.33%)**	**4/15 (26.67%)**	**11/61 (18.03%)**	**7/19 (36.84%)**
Blood and lymphatic system disorders				
anaemia † 2				
# participants affected / at risk	**0/48 (0.00%)**	**0/15 (0.00%)**	**0/61 (0.00%)**	**1/19 (5.26%)**
# events	**0**	**0**	**0**	**1**
bradyarrhythmia † 1				
# participants affected / at risk	**1/48 (2.08%)**	**0/15 (0.00%)**	**0/61 (0.00%)**	**0/19 (0.00%)**
# events	**1**	**0**	**0**	**0**
Cardiac disorders				

atrial fibrillation [†1]				
# participants affected / at risk	0/48 (0.00%)	0/15 (0.00%)	1/61 (1.64%)	0/19 (0.00%)
# events	0	0	1	0
cardiac arrest [†1]				
# participants affected / at risk	1/48 (2.08%)	0/15 (0.00%)	0/61 (0.00%)	0/19 (0.00%)
# events	1	0	0	0
cardiac failure congestive [†1]				
# participants affected / at risk	0/48 (0.00%)	0/15 (0.00%)	0/61 (0.00%)	1/19 (5.26%)
# events	0	0	0	1
cardio-respiratory arrest [†1]				
# participants affected / at risk	1/48 (2.08%)	0/15 (0.00%)	0/61 (0.00%)	0/19 (0.00%)
# events	1	0	0	0
myocardial infarction [†1]				
# participants affected / at risk	0/48 (0.00%)	0/15 (0.00%)	1/61 (1.64%)	1/19 (5.26%)
# events	0	0	1	1
ventricular arrhythmia [†1]				
# participants affected / at risk	0/48 (0.00%)	0/15 (0.00%)	0/61 (0.00%)	1/19 (5.26%)
# events	0	0	0	1
Gastrointestinal disorders				
colonic fistura [†1]				
# participants affected / at risk	0/48 (0.00%)	0/15 (0.00%)	1/61 (1.64%)	0/19 (0.00%)
# events	0	0	1	0
gasrointestinal haemorrhage [†1]				
# participants affected / at risk	0/48 (0.00%)	0/15 (0.00%)	0/61 (0.00%)	1/19 (5.26%)
# events	0	0	0	1
gastritis [†1]				
# participants affected / at risk	0/48 (0.00%)	0/15 (0.00%)	0/61 (0.00%)	1/19 (5.26%)
# events	0	0	0	1
intestinal infarction [†1]				
# participants affected / at risk	0/48 (0.00%)	1/15 (6.67%)	0/61 (0.00%)	0/19 (0.00%)
# events	0	1	0	0
intestinal ischaemia [†1]				
# participants affected / at risk	0/48 (0.00%)	0/15 (0.00%)	1/61 (1.64%)	0/19 (0.00%)
# events	0	0	1	0
megacolon [†1]				
# participants affected / at risk	1/48 (2.08%)	0/15 (0.00%)	0/61 (0.00%)	0/19 (0.00%)
# events	1	0	0	0
small intestinal obstruction [†1]				
# participants affected / at risk	0/48 (0.00%)	0/15 (0.00%)	1/61 (1.64%)	0/19 (0.00%)

# events	0	0	1	0
General disorders				
multi-organ failure † 1				
# participants affected / at risk	1/48 (2.08%)	0/15 (0.00%)	0/61 (0.00%)	0/19 (0.00%)
# events	1	0	0	0
Infections and infestations				
abdominal abscess † 1				
# participants affected / at risk	1/48 (2.08%)	0/15 (0.00%)	1/61 (1.64%)	1/19 (5.26%)
# events	1	0	1	1
endocarditis † 1				
# participants affected / at risk	1/48 (2.08%)	0/15 (0.00%)	0/61 (0.00%)	0/19 (0.00%)
# events	1	0	0	0
pelvic abscess † 1				
# participants affected / at risk	0/48 (0.00%)	0/15 (0.00%)	0/61 (0.00%)	1/19 (5.26%)
# events	0	0	0	1
pneumonia † 1				
# participants affected / at risk	1/48 (2.08%)	2/15 (13.33%)	0/61 (0.00%)	0/19 (0.00%)
# events	1	2	0	0
sepsis † 1				
# participants affected / at risk	1/48 (2.08%)	0/15 (0.00%)	2/61 (3.28%)	0/19 (0.00%)
# events	1	0	2	0
septic shock † 1				
# participants affected / at risk	1/48 (2.08%)	0/15 (0.00%)	0/61 (0.00%)	0/19 (0.00%)
# events	1	0	0	0
urinary tract infection † 1				
# participants affected / at risk	0/48 (0.00%)	0/15 (0.00%)	0/61 (0.00%)	1/19 (5.26%)
# events	0	0	0	1
abscess † 1				
# participants affected / at risk	0/48 (0.00%)	0/15 (0.00%)	0/61 (0.00%)	1/19 (5.26%)
# events	0	0	0	1
Injury, poisoning and procedural complications				
suture rupture † 1				
# participants affected / at risk	0/48 (0.00%)	0/15 (0.00%)	0/61 (0.00%)	1/19 (5.26%)
# events	0	0	0	1
wound dehiscence † 1				
# participants affected / at risk	0/48 (0.00%)	0/15 (0.00%)	1/61 (1.64%)	0/19 (0.00%)
# events	0	0	1	0
Metabolism and nutrition disorders				
hypoglycaemia † 1				

# participants affected / at risk	0/48 (0.00%)	0/15 (0.00%)	1/61 (1.64%)	0/19 (0.00%)
# events	0	0	1	0
Musculoskeletal and connective tissue disorders				
Fascitis † 1				
# participants affected / at risk	0/48 (0.00%)	0/15 (0.00%)	1/61 (1.64%)	0/19 (0.00%)
# events	0	0	1	0
Nervous system disorders				
Autonomic Nervous system imbalance † 1				
# participants affected / at risk	1/48 (2.08%)	0/15 (0.00%)	0/61 (0.00%)	0/19 (0.00%)
# events	1	0	0	0
brain oedema † 1				
# participants affected / at risk	1/48 (2.08%)	0/15 (0.00%)	0/61 (0.00%)	0/19 (0.00%)
# events	1	0	0	0
cerebrovascular accident † 1				
# participants affected / at risk	0/48 (0.00%)	0/15 (0.00%)	1/61 (1.64%)	0/19 (0.00%)
# events	0	0	1	0
hydrocephalus † 1				
# participants affected / at risk	1/48 (2.08%)	0/15 (0.00%)	0/61 (0.00%)	0/19 (0.00%)
# events	1	0	0	0
hypoglycaemic encephalopathy † 1				
# participants affected / at risk	1/48 (2.08%)	0/15 (0.00%)	0/61 (0.00%)	0/19 (0.00%)
# events	1	0	0	0
intracranial pressure increased † 1				
# participants affected / at risk	0/48 (0.00%)	1/15 (6.67%)	0/61 (0.00%)	0/19 (0.00%)
# events	0	1	0	0
Renal and urinary disorders				
renal failure † 1				
# participants affected / at risk	1/48 (2.08%)	0/15 (0.00%)	0/61 (0.00%)	0/19 (0.00%)
# events	1	0	0	0
renal failure acute † 1				
# participants affected / at risk	2/48 (4.17%)	0/15 (0.00%)	0/61 (0.00%)	0/19 (0.00%)
# events	2	0	0	0
Respiratory, thoracic and mediastinal disorders				
acute respiratory failure † 1				
# participants affected / at risk	0/48 (0.00%)	0/15 (0.00%)	1/61 (1.64%)	0/19 (0.00%)
# events	0	0	1	0
pulmonary embolism † 1				

# participants affected / at risk	2/48 (4.17%)	0/15 (0.00%)	0/61 (0.00%)	0/19 (0.00%)
# events	2	0	0	0
Vascular disorders				
haemorrhage † 1				
# participants affected / at risk	1/48 (2.08%)	0/15 (0.00%)	0/61 (0.00%)	0/19 (0.00%)
# events	1	0	0	0

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA (11.1)
2 Term from vocabulary, MedDRA 11.1

Other Adverse Events

Hide Other Adverse Events

Time Frame	All adverse events were reported from the time a signed and dated informed consent form was obtained until 30 days after the completion of study drug therapy
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
VAP Treated With Doripenem	Doripenem 1 g infused over 4 hours at 8-hour intervals for patients with Ventilator-Associated Pneumonia (VAP) for 7-14 days
VAP Treated With Imipenem/Cilastatin	Imipenem/cilastatin 1 g infused over 1 hour at 8-hour intervals for patients with Ventilator-Associated Pneumonia (VAP)for 7-14 days
cIAI Treated With Doripenem	Doripenem 1 g infused over 4 hours at 8-hour intervals for patients with complicated Intra-Abdominal Infection (cIAI) for 5-14 days
cIAI Treated With Imipenem/Cilastatin	Imipenem/cilastatin 1 g infused over 1 hour at 8-hour intervals for patients with complicated Intra-Abdominal Infection (cIAI) for 5-14 days

Other Adverse Events

	VAP Treated With Doripenem	VAP Treated With Imipenem/Cilastatin	cIAI Treated With Doripenem	cIAI Treated With Imipenem/Cilastatin
Total, other (not including serious) adverse events				
# participants affected / at risk	42/48 (87.50%)	13/15 (86.67%)	37/61 (60.66%)	15/19 (78.95%)
Blood and lymphatic system disorders				
Anaemia † 1				
# participants affected / at risk	9/48 (18.75%)	1/15 (6.67%)	1/61 (1.64%)	1/19 (5.26%)
# events	9	1	1	1
Gastrointestinal disorders				
constipation † 1				
# participants affected / at risk	3/48 (6.25%)	3/15 (20.00%)	1/61 (1.64%)	2/19 (10.53%)

# events	3	3	1	2
diarrhoea [†1]				
# participants affected / at risk	6/48 (12.50%)	2/15 (13.33%)	3/61 (4.92%)	1/19 (5.26%)
# events	6	2	3	1
nausea [†1]				
# participants affected / at risk	2/48 (4.17%)	0/15 (0.00%)	6/61 (9.84%)	0/19 (0.00%)
# events	2	0	6	0
Abdominal Distension [†1]				
# participants affected / at risk	3/48 (6.25%)	0/15 (0.00%)	0/61 (0.00%)	1/19 (5.26%)
# events	3	0	0	1
Viomiting [†1]				
# participants affected / at risk	1/48 (2.08%)	1/15 (6.67%)	3/61 (4.92%)	0/19 (0.00%)
# events	1	1	3	0
General disorders				
pyrexia [†1]				
# participants affected / at risk	5/48 (10.42%)	2/15 (13.33%)	5/61 (8.20%)	3/19 (15.79%)
# events	5	2	5	3
Oedema Peripheral [†1]				
# participants affected / at risk	4/48 (8.33%)	0/15 (0.00%)	1/61 (1.64%)	0/19 (0.00%)
# events	4	0	1	0
Infections and infestations				
pneumonia [†1]				
# participants affected / at risk	3/48 (6.25%)	2/15 (13.33%)	0/61 (0.00%)	3/19 (15.79%)
# events	3	2	0	3
urinary tract infection [†1]				
# participants affected / at risk	5/48 (10.42%)	3/15 (20.00%)	0/61 (0.00%)	1/19 (5.26%)
# events	5	3	0	1
Oral Candidiasis [†1]				
# participants affected / at risk	0/48 (0.00%)	0/15 (0.00%)	3/61 (4.92%)	1/19 (5.26%)
# events	0	0	3	1
Urinary Tract Infection Fungal [†1]				
# participants affected / at risk	3/48 (6.25%)	0/15 (0.00%)	0/61 (0.00%)	0/19 (0.00%)
# events	3	0	0	0
Wound Infection [†1]				
# participants affected / at risk	3/48 (6.25%)	1/15 (6.67%)	0/61 (0.00%)	0/19 (0.00%)
# events	3	1	0	0
Injury, poisoning and procedural complications				
Wound Dehiscence [†1]				
# participants affected / at risk	1/48 (2.08%)	0/15 (0.00%)	3/61 (4.92%)	1/19 (5.26%)

# events	1	0	3	1
Investigations				
Hepatic Enzyme Increased [†1]				
# participants affected / at risk	3/48 (6.25%)	0/15 (0.00%)	0/61 (0.00%)	0/19 (0.00%)
# events	3	0	0	0
Metabolism and nutrition disorders				
hypoglycaemia [†1]				
# participants affected / at risk	2/48 (4.17%)	0/15 (0.00%)	4/61 (6.56%)	0/19 (0.00%)
# events	2	0	4	0
hypokalaemia [†1]				
# participants affected / at risk	4/48 (8.33%)	1/15 (6.67%)	4/61 (6.56%)	3/19 (15.79%)
# events	4	1	4	3
Hypomagnesaemia [†1]				
# participants affected / at risk	3/48 (6.25%)	0/15 (0.00%)	1/61 (1.64%)	1/19 (5.26%)
# events	3	0	1	1
Nervous system disorders				
Headache [†1]				
# participants affected / at risk	1/48 (2.08%)	0/15 (0.00%)	4/61 (6.56%)	0/19 (0.00%)
# events	1	0	4	0
Psychiatric disorders				
insomnia [†1]				
# participants affected / at risk	2/48 (4.17%)	1/15 (6.67%)	0/61 (0.00%)	2/19 (10.53%)
# events	2	1	0	2
Anxiety [†1]				
# participants affected / at risk	2/48 (4.17%)	0/15 (0.00%)	2/61 (3.28%)	1/19 (5.26%)
# events	2	0	2	1
Respiratory, thoracic and mediastinal disorders				
bronchospasm [†1]				
# participants affected / at risk	6/48 (12.50%)	0/15 (0.00%)	0/61 (0.00%)	0/19 (0.00%)
# events	6	0	0	0
Pleural Effusion [†1]				
# participants affected / at risk	4/48 (8.33%)	0/15 (0.00%)	0/61 (0.00%)	1/19 (5.26%)
# events	4	0	0	1
Pulmonary Embolism [†1]				
# participants affected / at risk	3/48 (6.25%)	0/15 (0.00%)	0/61 (0.00%)	0/19 (0.00%)
# events	3	0	0	0
Skin and subcutaneous tissue disorders				
decubitus ulcer [†1]				
	6/48 (12.50%)	0/15 (0.00%)	0/61 (0.00%)	0/19 (0.00%)

# participants affected / at risk				
# events	**6**	**0**	**0**	**0**
Skin Lesion † 1				
# participants affected / at risk	**3/48 (6.25%)**	**0/15 (0.00%)**	**1/61 (1.64%)**	**0/19 (0.00%)**
# events	**3**	**0**	**1**	**0**
Vascular disorders				
hypertension † 1				
# participants affected / at risk	**2/48 (4.17%)**	**1/15 (6.67%)**	**7/61 (11.48%)**	**2/19 (10.53%)**
# events	**2**	**1**	**7**	**2**
hypotension † 1				
# participants affected / at risk	**4/48 (8.33%)**	**0/15 (0.00%)**	**2/61 (3.28%)**	**0/19 (0.00%)**
# events	**4**	**0**	**2**	**0**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA (11.1)

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
open-label study design and limited number of subjects in the comparator group

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.

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No publications provided

Responsible Party:	Senior Director Clinical Development, Johnson & Johnson Pharmaceutical Research and Development, L.L.C.
ClinicalTrials.gov Identifier:	NCT00515034 History of Changes
Other Study ID Numbers:	**CR012934**, DORINOS2001
Study First Received:	August 10, 2007
Results First Received:	November 13, 2009
Last Updated:	May 9, 2011
Health Authority:	United States: Food and Drug Administration

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