A Multicenter, Randomized, Double-Blind, Comparative Study to Evaluate the Safety, Tolerability, and Efficacy of 2 Dosing Regimens of an Antifungal Drug in the Treatment of Fungal Infections in Adults (0991-801)(COMPLETED)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

Information provided by (Responsible Party):
Merck Sharp & Dohme Corp.

ClinicalTrials.gov Identifier:
NCT00250432

First received: November 4, 2005
Last updated: September 24, 2015
Last verified: September 2015
History of Changes

Purpose

Comparison of the safety and effectiveness of standard drug dosing versus a daily dose 3 times higher than the standard dose in patients with invasive candidiasis (bloodstream and/or systemic yeast infections)

Condition	Intervention	Phase
Invasive Candidiasis	Drug: caspofungin acetate	Phase 3

Study Type: Interventional
Study Design: Allocation: Randomized
Endpoint Classification: Safety Study
Intervention Model: Parallel Assignment
Masking: Double Blind (Subject, Investigator)
Primary Purpose: Treatment

Official Title: A Multicenter, Randomized, Double-Blind, Comparative Study to Evaluate the Safety, Tolerability, and Efficacy of 2 Dosing Regimens of Caspofungin in the Treatment of Invasive Candidiasis in Adults

Resource links provided by NLM:

MedlinePlus related topics: Yeast Infections

Drug Information available for: Caspofungin Caspofungin acetate

Genetic and Rare Diseases Information Center resources: Systemic Candidiasis

U.S. FDA Resources

Further study details as provided by Merck Sharp & Dohme Corp.:

Primary Outcome Measures:

- Number of Patients Who Develop Significant Drug-related Adverse Events. [Time Frame: 90 Days] [Designated as safety issue: Yes]

  Number of patients with at least 1 significant drug-related adverse event (serious drug-related or drug-related adverse events leading to caspofungin discontinuation) while on caspofungin study therapy or during the immediate 14-day post-caspofungin therapy period.

Secondary Outcome Measures:

- Number of Patients With a Favorable Overall Response. [Time Frame: 90 Days] [Designated as safety issue: No]

  Number of patients with a favorable overall response, defined as a clinical response of "cure" or "apparent cure" along with a microbiological response of "eradication" or "presumptive eradication" at the End of Caspofungin Therapy.

Enrollment:	204
Study Start Date:	January 2006
Study Completion Date:	March 2008
Primary Completion Date:	January 2008 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Active Comparator: 1 50 mg intravenous (IV) infusion (diluted with 9% saline) administered daily (following a 70-mg IV loading dose on Day 1), over the course of ~2 hrs. all patients should be treated with antifungal therapy for at least 14 days following both the improvement in clinical and radiographic signs of disease and the eradication of Candida from culture samples obtained from the invasive site of infection.	Drug: caspofungin acetate Caspofungin acetate 50 mg IV infusion (diluted with 9% saline) (following a 70-mg IV loading dose on Day 1); Caspofungin acetate 150 mg IV infusion (diluted with 9% saline) administered daily, over the course of ~2 hrs. Duration of Treatment - 14-90 days.
Experimental: 2 150 mg intravenous (IV) infusion (diluted with 9% saline) administered daily, over the course of ~2 hrs. all patients should be treated with antifungal therapy for at least 14 days following both the improvement in clinical and radiographic signs of disease and the eradication of Candida from culture samples obtained from the invasive site of infection.	Drug: caspofungin acetate Caspofungin acetate 50 mg IV infusion (diluted with 9% saline) (following a 70-mg IV loading dose on Day 1); Caspofungin acetate 150 mg IV infusion (diluted with 9% saline) administered daily, over the course of ~2 hrs. Duration of Treatment - 14-90 days.

Eligibility

Ages Eligible for Study:	18 Years and older
Genders Eligible for Study:	Both
Accepts Healthy Volunteers:	No

Criteria

Inclusion Criteria:

- Clinical and Laboratory evidence of blood stream &/or systemic candida infections

Exclusion Criteria:

- Possible candida contamination
- Candida colonization (non invasive infection), urine, cardiac, bone or brain and prosthetic device infections
- Acute or moderately severe liver disease
- Abnormal liver function tests
- Abnormal blood clotting for patients on blood thinners

Contacts and Locations

Choosing to participate in a study is an important personal decision. Talk with your doctor and family members or friends about deciding to join a study. To learn more about this study, you or your doctor may contact the study research staff using the Contacts provided below. For general information, see Learn About Clinical Studies.

Please refer to this study by its ClinicalTrials.gov identifier: NCT00250432

Sponsors and Collaborators

Merck Sharp & Dohme Corp.

Investigators

Study Director: Medical Monitor Merck Sharp & Dohme Corp.

More Information

Additional Information:

MedWatch - FDA maintained medical product safety Information EXIT

Merck: Patient & Caregiver U.S. Product Web Site EXIT

Publications:

Betts RF, Nucci M, Talwar D, Gareca M, Queiroz-Telles F, Bedimo RJ, Herbrecht R, Ruiz-Palacios G, Young JA, Baddley JW, Strohmaier KM, Tucker KA, Taylor AF, Kartsonis NA; Caspofungin High-Dose Study Group. A Multicenter, double-blind trial of a high-dose caspofungin treatment regimen versus a standard caspofungin treatment regimen for adult patients with invasive candidiasis. Clin Infect Dis. 2009 Jun 15;48(12):1676-84. doi: 10.1086/598933.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00250432 History of Changes
Other Study ID Numbers:	0991-801 2005_085
Study First Received:	November 4, 2005
Results First Received:	January 13, 2009
Last Updated:	September 24, 2015
Health Authority:	United States: Food and Drug Administration

Additional relevant MeSH terms:

Candidiasis	Anti-Infective Agents
Candidiasis, Invasive	Antifungal Agents
Mycoses	Pharmacologic Actions
Caspofungin	Therapeutic Uses
Echinocandins	

ClinicalTrials.gov processed this record on May 08, 2016

TO TOP

For Patients and Families | For Researchers | For Study Record Managers

HOME RSS FEEDS SITE MAP TERMS AND CONDITIONS DISCLAIMER CONTACT NLM HELP DESK

A Multicenter, Randomized, Double-Blind, Comparative Study to Evaluate the Safety, Tolerability, and Efficacy of 2 Dosing Regimens of an Antifungal Drug in the Treatment of Fungal Infections in Adults (0991-801)(COMPLETED)

This study has been completed.

Sponsor:
Merck Sharp & Dohme Corp.

Information provided by (Responsible Party):
Merck Sharp & Dohme Corp.

ClinicalTrials.gov Identifier:
NCT00250432

First received: November 4, 2005
Last updated: September 24, 2015
Last verified: September 2015
History of Changes

Results First Received: January 13, 2009

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Condition:	Invasive Candidiasis
Intervention:	Drug: caspofungin acetate

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
This was a Phase III study. The first patient was enrolled (FPE) on 13-Jan-2006. The last patient's last visit (LPLV) was on 13-Mar-2008. A total of 38 inpatient centers were involved in the recruitment worldwide (14 in the United States, 13 in the European Union, 7 in Central or South America, and 4 in Asia)

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
Caspofungin 70/50 mg	Caspofungin 50 mg IV daily (following a 70-mg IV loading dose on Day 1)
Caspofungin 150 mg	Caspofungin 150 mg IV daily

Participant Flow: Overall Study

	Caspofungin 70/50 mg	Caspofungin 150 mg
STARTED	**104**	**100**
COMPLETED	**59**	**53**
NOT COMPLETED	**45**	**47**
Adverse Event	**25**	**29**
Lack of Efficacy	**2**	**1**
Lost to Follow-up	**6**	**5**
Patient Moved	**0**	**1**
Protocol Violation	**0**	**3**
Withdrawal by Subject	**6**	**2**
Pt died out of posttherapy report period	**6**	**5**
Pt was considered untreatable	**0**	**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
Caspofungin 70/50 mg	Caspofungin 50 mg IV daily (following a 70-mg IV loading dose on Day 1)
Caspofungin 150 mg	Caspofungin 150 mg IV daily
Total	Total of all reporting groups

Baseline Measures

	Caspofungin 70/50 mg	Caspofungin 150 mg	Total
Number of Participants [units: participants]	**104**	**100**	**204**
Age [units: years]	**56.0 (16 to 90)**	**57.8 (20 to 87)**	**56.9 (16 to 90)**

Mean (Full Range)			
Gender [units: participants]			
Female	**50**	**40**	**90**
Male	**54**	**60**	**114**
Race/Ethnicity, Customized [units: participants]			
Caucasian	**70**	**65**	**135**
Black	**11**	**12**	**23**
Asian	**17**	**16**	**33**
Hispanic	**4**	**5**	**9**
Other	**2**	**2**	**4**
Site Of Invasive Candida Infection [1] [units: Participants]			
Abscess(involving an intra-abdominal site)	**0**	**2**	**2**
Abscess (involving a non-abdominal site)	**0**	**1**	**1**
Acute disseminated candidiasis or multiple sites	**6**	**7**	**13**
Blood (candidemia)	**91**	**81**	**172**
Chronic disseminated candidiasis (hepatosplenic)	**1**	**0**	**1**
Fungemia (non Candida)	**0**	**2**	**2**
Kidney (Pyelonephritis)	**0**	**1**	**1**
Lung (Pneumonia)	**1**	**1**	**2**
Peritoneal fluid (Peritonitis)	**4**	**5**	**9**
Pleural fluid (Empyema)	**1**	**0**	**1**
APACHE II Score (at Study Entry) [2] [units: Units on a Scale] Mean (Full Range)	**16.5 (3 to 38)**	**17.0 (2 to 39)**	**16.8 (2 to 39)**

[1] This table lists the site of invasive candidiasis. Patients are included in only 1 category. Patients with more than 1 site of infection are counted under "Acute disseminated candidiasis or multiple sites".

[2] APACHE (Acute Physiology and Chronic Health Evaluation) is a system of classifying severity of illnesses in intensive care patients. The possible range of values is 0 (minimum severity) to 71 (maximum severity).

Outcome Measures

Hide All Outcome Measures

1. Primary: Number of Patients Who Develop Significant Drug-related Adverse Events. [Time Frame: 90 Days]

Measure Type	Primary
Measure Title	Number of Patients Who Develop Significant Drug-related Adverse Events.
Measure Description	Number of patients with at least 1 significant drug-related adverse event (serious drug-related or drug-related adverse events leading to caspofungin discontinuation) while on caspofungin study therapy or during the immediate 14-day post-caspofungin therapy period.

Time Frame	90 Days
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.
All patients as treated population

Reporting Groups

	Description
Caspofungin 70/50 mg	Caspofungin 50 mg IV daily (following a 70-mg IV loading dose on Day 1)
Caspofungin 150 mg	Caspofungin 150 mg IV daily

Measured Values

	Caspofungin 70/50 mg	**Caspofungin 150 mg**
Number of Participants Analyzed [units: participants]	**104**	**100**
Number of Patients Who Develop Significant Drug-related Adverse Events. [units: Participants]	**2**	**3**

Statistical Analysis 1 for Number of Patients Who Develop Significant Drug-related Adverse Events.

Groups [1]	All groups
Non-Inferiority/Equivalence Test [2]	Yes
Rate Difference [3]	1.1
Standard Error of the mean	(5.6)
95% Confidence Interval	-4.1 to 6.8

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	A significant drug-related adverse event was defined as either a drug-related serious adverse event or a drug-related adverse event leading to discontinuation of caspofungin therapy. Comparison between the 2 caspofungin groups was based on upper bound of the 95% confidence interval for the difference.
[2]	Details of power calculation, definition of non-inferiority margin, and other key parameters:
	Safety with caspofungin 150 mg daily will be non-inferior to that of caspofungin 70/50 mg. Non-inferiority was defined as upper limit of the 2-sided, 95% confidence interval for the difference (150-mg group - 70/50-mg group) must be less than 0.15 (15 percentage points).
[3]	Other relevant estimation information:
	The confidence interval computation was based on the method by Miettinen and Nurminen.

2. Secondary: Number of Patients With a Favorable Overall Response. [Time Frame: 90 Days]

Measure Type	Secondary
Measure Title	Number of Patients With a Favorable Overall Response.
Measure Description	Number of patients with a favorable overall response, defined as a clinical response of "cure" or "apparent cure" along with a microbiological response of "eradication" or "presumptive eradication" at the End of Caspofungin Therapy.
Time Frame	90 Days
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.
Full Analysis Set (FAS): Included those patients who received at least 1 full dose of caspofungin study therapy and had a documented diagnosis of invasive candidiasis from a sterile, invasive body site, as defined in the protocol.

Reporting Groups

	Description
Caspofungin 70/50 mg	Caspofungin 50 mg IV daily (following a 70-mg IV loading dose on Day 1)
Caspofungin 150 mg	Caspofungin 150 mg IV daily

Measured Values

	Caspofungin 70/50 mg	**Caspofungin 150 mg**
Number of Participants Analyzed [units: participants]	**102**	**95**
Number of Patients With a Favorable Overall Response. [units: Participants]	**73**	**74**

Statistical Analysis 1 for Number of Patients With a Favorable Overall Response.

Groups [1]	All groups
Rate Difference [2]	6.3
Standard Error of the mean	(12.1)
95% Confidence Interval	-5.9 to 18.4

[1]	Additional details about the analysis, such as null hypothesis and power calculation:
	There was no formal hypothesis testing for efficacy in this study. The main efficacy analysis was the number (percentage) of patients with a favorable overall response at the end of caspofungin study therapy, together with the within treatment 95% exact binomial confidence intervals, and the estimated treatment difference, and its 95% confidence interval.
[2]	Other relevant estimation information:
	The 95% confidence interval on the difference will be based on the method of Miettinen and Nurminen.

Serious Adverse Events

Hide Serious Adverse Events

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

Reporting Groups

	Description
Caspofungin 70/50 mg	Caspofungin 50 mg IV daily (following a 70-mg IV loading dose on Day 1)
Caspofungin 150 mg	Caspofungin 150 mg IV daily

Serious Adverse Events

	Caspofungin 70/50 mg	Caspofungin 150 mg
Total, serious adverse events		
# participants affected	**46**	**44**
Blood and lymphatic system disorders		
Leukopenia [*1]		
# participants affected / at risk	**0/104 (0.00%)**	**1/100 (1.00%)**
Cardiac disorders		
Acute Myocardial Infarction [*1]		
# participants affected / at risk	**1/104 (0.96%)**	**0/100 (0.00%)**
Arrhythmia [*1]		
# participants affected / at risk	**0/104 (0.00%)**	**1/100 (1.00%)**
Atrioventricular Block [*1]		
# participants affected / at risk	**0/104 (0.00%)**	**1/100 (1.00%)**
Atrioventricular Block Complete [*1]		
# participants affected / at risk	**1/104 (0.96%)**	**0/100 (0.00%)**
Bradycardia [*1]		
# participants affected / at risk	**0/104 (0.00%)**	**1/100 (1.00%)**
Cardiac Arrest [*1]		
# participants affected / at risk	**1/104 (0.96%)**	**1/100 (1.00%)**
Cardiac Failure Congestive [*1]		
# participants affected / at risk	**0/104 (0.00%)**	**1/100 (1.00%)**
Cardio-Respiratory Arrest [*1]		
# participants affected / at risk	**2/104 (1.92%)**	**0/100 (0.00%)**
Electromechanical Disorder [*1]		
# participants affected / at risk	**1/104 (0.96%)**	**0/100 (0.00%)**
Gastrointestinal disorders		
Gastrointestinal Haemorrhage [*1]		

# participants affected / at risk	1/104 (0.96%)	1/100 (1.00%)
Gastrointestinal Ulcer Perforation [*1]		
# participants affected / at risk	0/104 (0.00%)	1/100 (1.00%)
Haematemesis [*1]		
# participants affected / at risk	1/104 (0.96%)	0/100 (0.00%)
Intestinal Obstruction [*1]		
# participants affected / at risk	0/104 (0.00%)	1/100 (1.00%)
Intra-Abdominal Haemorrhage [*1]		
# participants affected / at risk	0/104 (0.00%)	1/100 (1.00%)
Lower Gastrointestinal Haemorrhage [*1]		
# participants affected / at risk	1/104 (0.96%)	0/100 (0.00%)
Peritoneal Haemorrhage [*1]		
# participants affected / at risk	0/104 (0.00%)	1/100 (1.00%)
Vomiting [*1]		
# participants affected / at risk	1/104 (0.96%)	0/100 (0.00%)
General disorders		
Brain Death [*1]		
# participants affected / at risk	1/104 (0.96%)	0/100 (0.00%)
Death [*1]		
# participants affected / at risk	2/104 (1.92%)	0/100 (0.00%)
General Physical Health Deterioration [*1]		
# participants affected / at risk	1/104 (0.96%)	0/100 (0.00%)
Multi-Organ Failure [*1]		
# participants affected / at risk	5/104 (4.81%)	4/100 (4.00%)
Non-Cardiac Chest Pain [*1]		
# participants affected / at risk	1/104 (0.96%)	0/100 (0.00%)
Pyrexia [*1]		
# participants affected / at risk	1/104 (0.96%)	0/100 (0.00%)
Systemic Inflammatory Response Syndrome [*1]		
# participants affected / at risk	0/104 (0.00%)	1/100 (1.00%)
Hepatobiliary disorders		
Hepatitis Toxic [*1]		
# participants affected / at risk	0/104 (0.00%)	1/100 (1.00%)
Hyperbilirubinaemia [*1]		
# participants affected / at risk	0/104 (0.00%)	1/100 (1.00%)
Jaundice Cholestatic [*1]		
# participants affected / at risk	1/104 (0.96%)	0/100 (0.00%)
Infections and infestations		
Abdominal Sepsis [*1]		
# participants affected / at risk	0/104 (0.00%)	2/100 (2.00%)
Bacteraemia [*1]		

# participants affected / at risk	2/104 (1.92%)	0/100 (0.00%)
Cellulitis [*1]		
# participants affected / at risk	2/104 (1.92%)	0/100 (0.00%)
Cholecystitis Infective [*1]		
# participants affected / at risk	0/104 (0.00%)	1/100 (1.00%)
Clostridial Infection [*1]		
# participants affected / at risk	1/104 (0.96%)	0/100 (0.00%)
Enterococcal Bacteraemia [*1]		
# participants affected / at risk	0/104 (0.00%)	2/100 (2.00%)
Fungaemia [*1]		
# participants affected / at risk	2/104 (1.92%)	0/100 (0.00%)
Fungal Sepsis [*1]		
# participants affected / at risk	0/104 (0.00%)	1/100 (1.00%)
Klebsiella Bacteraemia [*1]		
# participants affected / at risk	0/104 (0.00%)	1/100 (1.00%)
Lower Respiratory Tract Infection [*1]		
# participants affected / at risk	0/104 (0.00%)	1/100 (1.00%)
Meningitis Aseptic [*1]		
# participants affected / at risk	1/104 (0.96%)	0/100 (0.00%)
Pneumonia [*1]		
# participants affected / at risk	3/104 (2.88%)	4/100 (4.00%)
Pneumonia Staphylococcal [*1]		
# participants affected / at risk	1/104 (0.96%)	0/100 (0.00%)
Pseudomonal Bacteraemia [*1]		
# participants affected / at risk	0/104 (0.00%)	1/100 (1.00%)
Sepsis [*1]		
# participants affected / at risk	5/104 (4.81%)	6/100 (6.00%)
Septic Shock [*1]		
# participants affected / at risk	12/104 (11.54%)	13/100 (13.00%)
Stenotrophomonas Infection [*1]		
# participants affected / at risk	0/104 (0.00%)	1/100 (1.00%)
Systemic Candida [*1]		
# participants affected / at risk	1/104 (0.96%)	1/100 (1.00%)
Urosepsis [*1]		
# participants affected / at risk	0/104 (0.00%)	1/100 (1.00%)
Wound Infection [*1]		
# participants affected / at risk	1/104 (0.96%)	0/100 (0.00%)
Injury, poisoning and procedural complications		
Accidental Overdose [*1]		
# participants affected / at risk	0/104 (0.00%)	1/100 (1.00%)
Tracheal Obstruction [*1]		

# participants affected / at risk	0/104 (0.00%)	1/100 (1.00%)
Musculoskeletal and connective tissue disorders		
Joint Swelling [*1]		
# participants affected / at risk	0/104 (0.00%)	1/100 (1.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)		
Adenocarcinoma [*1]		
# participants affected / at risk	0/104 (0.00%)	1/100 (1.00%)
Chronic Myeloid Leukaemia [*1]		
# participants affected / at risk	1/104 (0.96%)	0/100 (0.00%)
Colon Cancer Metastatic [*1]		
# participants affected / at risk	0/104 (0.00%)	1/100 (1.00%)
Metastases To Lung [*1]		
# participants affected / at risk	1/104 (0.96%)	0/100 (0.00%)
Pituitary Cancer Metastatic [*1]		
# participants affected / at risk	1/104 (0.96%)	0/100 (0.00%)
Tumour Necrosis [*1]		
# participants affected / at risk	1/104 (0.96%)	0/100 (0.00%)
Nervous system disorders		
Cerebral Haematoma [*1]		
# participants affected / at risk	1/104 (0.96%)	0/100 (0.00%)
Convulsion [*1]		
# participants affected / at risk	2/104 (1.92%)	0/100 (0.00%)
Myasthenia Gravis [*1]		
# participants affected / at risk	0/104 (0.00%)	1/100 (1.00%)
Partial Seizures [*1]		
# participants affected / at risk	0/104 (0.00%)	1/100 (1.00%)
Renal and urinary disorders		
Oliguria [*1]		
# participants affected / at risk	0/104 (0.00%)	1/100 (1.00%)
Renal Failure Acute [*1]		
# participants affected / at risk	2/104 (1.92%)	2/100 (2.00%)
Respiratory, thoracic and mediastinal disorders		
Acute Pulmonary Oedema [*1]		
# participants affected / at risk	1/104 (0.96%)	0/100 (0.00%)
Acute Respiratory Distress Syndrome [*1]		
# participants affected / at risk	2/104 (1.92%)	3/100 (3.00%)
Acute Respiratory Failure [*1]		
# participants affected / at risk	1/104 (0.96%)	1/100 (1.00%)
Hypercapnia [*1]		
# participants affected / at risk	1/104 (0.96%)	0/100 (0.00%)

Lung Infiltration * 1		
# participants affected / at risk	**0/104 (0.00%)**	**1/100 (1.00%)**
Pleural Effusion * 1		
# participants affected / at risk	**0/104 (0.00%)**	**1/100 (1.00%)**
Pneumonia Aspiration * 1		
# participants affected / at risk	**1/104 (0.96%)**	**0/100 (0.00%)**
Pulmonary Embolism * 1		
# participants affected / at risk	**1/104 (0.96%)**	**1/100 (1.00%)**
Pulmonary Oedema * 1		
# participants affected / at risk	**0/104 (0.00%)**	**1/100 (1.00%)**
Respiratory Arrest * 1		
# participants affected / at risk	**2/104 (1.92%)**	**1/100 (1.00%)**
Respiratory Disorder * 1		
# participants affected / at risk	**0/104 (0.00%)**	**1/100 (1.00%)**
Respiratory Failure * 1		
# participants affected / at risk	**6/104 (5.77%)**	**1/100 (1.00%)**
Vascular disorders		
Haemodynamic Instability * 1		
# participants affected / at risk	**0/104 (0.00%)**	**1/100 (1.00%)**
Peripheral Vascular Disorder * 1		
# participants affected / at risk	**0/104 (0.00%)**	**1/100 (1.00%)**
Shock Haemorrhage * 1		
# participants affected / at risk	**0/104 (0.00%)**	**1/100 (1.00%)**
Venous Thrombosis Limb * 1		
# participants affected / at risk	**1/104 (0.96%)**	**0/100 (0.00%)**

* Events were collected by non-systematic assessment

1 Term from vocabulary, MedDRA 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	2%

Reporting Groups

	Description
Caspofungin 70/50 mg	Caspofungin 50 mg IV daily (following a 70-mg IV loading dose on Day

	1)
Caspofungin 150 mg	Caspofungin 150 mg IV daily

Other Adverse Events

	Caspofungin 70/50 mg	Caspofungin 150 mg
Total, other (not including serious) adverse events		
# participants affected	**69**	**70**
Blood and lymphatic system disorders		
Anaemia [*1]		
# participants affected / at risk	**3/104 (2.88%)**	**4/100 (4.00%)**
Cardiac disorders		
Atrial Fibrillation [*1]		
# participants affected / at risk	**0/104 (0.00%)**	**3/100 (3.00%)**
Bradycardia [*1]		
# participants affected / at risk	**2/104 (1.92%)**	**2/100 (2.00%)**
Tachycardia [*1]		
# participants affected / at risk	**1/104 (0.96%)**	**2/100 (2.00%)**
Ventricular Tachycardia [*1]		
# participants affected / at risk	**3/104 (2.88%)**	**2/100 (2.00%)**
Endocrine disorders		
Adrenal Insufficiency [*1]		
# participants affected / at risk	**0/104 (0.00%)**	**2/100 (2.00%)**
Gastrointestinal disorders		
Abdominal Pain [*1]		
# participants affected / at risk	**3/104 (2.88%)**	**0/100 (0.00%)**
Abdominal Pain Upper [*1]		
# participants affected / at risk	**2/104 (1.92%)**	**3/100 (3.00%)**
Constipation [*1]		
# participants affected / at risk	**3/104 (2.88%)**	**3/100 (3.00%)**
Diarrhea [*1]		
# participants affected / at risk	**6/104 (5.77%)**	**7/100 (7.00%)**
Gastrointestinal Hemorrhage [*1]		
# participants affected / at risk	**1/104 (0.96%)**	**2/100 (2.00%)**
Haematemesis [*1]		
# participants affected / at risk	**0/104 (0.00%)**	**2/100 (2.00%)**
Ileus [*1]		
# participants affected / at risk	**3/104 (2.88%)**	**1/100 (1.00%)**
Nausea [*1]		
# participants affected / at risk	**5/104 (4.81%)**	**7/100 (7.00%)**
Vomiting [*1]		

# participants affected / at risk	10/104 (9.62%)	6/100 (6.00%)
General disorders		
Asthenia [*1]		
# participants affected / at risk	2/104 (1.92%)	3/100 (3.00%)
Chest Pain [*1]		
# participants affected / at risk	1/104 (0.96%)	2/100 (2.00%)
Generalised Oedema [*1]		
# participants affected / at risk	3/104 (2.88%)	0/100 (0.00%)
Hypothermia [*1]		
# participants affected / at risk	2/104 (1.92%)	2/100 (2.00%)
Injection Site Erythema [*1]		
# participants affected / at risk	0/104 (0.00%)	2/100 (2.00%)
Injection Site Phlebitis [*1]		
# participants affected / at risk	4/104 (3.85%)	2/100 (2.00%)
Injection Site Swelling [*1]		
# participants affected / at risk	1/104 (0.96%)	2/100 (2.00%)
Oedema [*1]		
# participants affected / at risk	1/104 (0.96%)	2/100 (2.00%)
Oedema Peripheral [*1]		
# participants affected / at risk	4/104 (3.85%)	2/100 (2.00%)
Pyrexia [*1]		
# participants affected / at risk	5/104 (4.81%)	6/100 (6.00%)
Hepatobiliary disorders		
Jaundice [*1]		
# participants affected / at risk	0/104 (0.00%)	2/100 (2.00%)
Infections and infestations		
Bacteraemia [*1]		
# participants affected / at risk	3/104 (2.88%)	2/100 (2.00%)
Empyema [*1]		
# participants affected / at risk	1/104 (0.96%)	2/100 (2.00%)
Pneumonia [*1]		
# participants affected / at risk	2/104 (1.92%)	4/100 (4.00%)
Staphylococcal Bacteraemia [*1]		
# participants affected / at risk	3/104 (2.88%)	4/100 (4.00%)
Urinary Tract Infection [*1]		
# participants affected / at risk	3/104 (2.88%)	2/100 (2.00%)
Investigations		
Activated Partial Thromboplastin Time Prolonged [*1]		
# participants affected / at risk	0/104 (0.00%)	2/100 (2.00%)
Alanine Aminotransferase Increased [*1]		

# participants affected / at risk	4/104 (3.85%)	7/100 (7.00%)
Aspartate Aminotransferase Increased [*1]		
# participants affected / at risk	6/104 (5.77%)	9/100 (9.00%)
Blood Albumin Decreased [*1]		
# participants affected / at risk	2/104 (1.92%)	2/100 (2.00%)
Blood Alkaline Phosphatase Increased [*1]		
# participants affected / at risk	12/104 (11.54%)	9/100 (9.00%)
Blood Bilirubin Increased [*1]		
# participants affected / at risk	3/104 (2.88%)	2/100 (2.00%)
Blood Calcium Decreased [*1]		
# participants affected / at risk	1/104 (0.96%)	2/100 (2.00%)
Blood Calcium Increased [*1]		
# participants affected / at risk	0/104 (0.00%)	2/100 (2.00%)
Blood Chloride Increased [*1]		
# participants affected / at risk	0/104 (0.00%)	3/100 (3.00%)
Blood Creatinine Increased [*1]		
# participants affected / at risk	3/104 (2.88%)	3/100 (3.00%)
Blood Glucose Decreased [*1]		
# participants affected / at risk	3/104 (2.88%)	1/100 (1.00%)
Blood Glucose Increased [*1]		
# participants affected / at risk	1/104 (0.96%)	3/100 (3.00%)
Blood Magnesium Decreased [*1]		
# participants affected / at risk	4/104 (3.85%)	4/100 (4.00%)
Blood Phosphorus Decreased [*1]		
# participants affected / at risk	2/104 (1.92%)	2/100 (2.00%)
Blood Potassium Decreased [*1]		
# participants affected / at risk	6/104 (5.77%)	8/100 (8.00%)
Blood Potassium Increased [*1]		
# participants affected / at risk	2/104 (1.92%)	4/100 (4.00%)
Blood Sodium Decreased [*1]		
# participants affected / at risk	1/104 (0.96%)	3/100 (3.00%)
Blood Sodium Increased [*1]		
# participants affected / at risk	2/104 (1.92%)	4/100 (4.00%)
Blood Urea Increased [*1]		
# participants affected / at risk	4/104 (3.85%)	1/100 (1.00%)
Blood Uric Acid Decreased [*1]		
# participants affected / at risk	0/104 (0.00%)	2/100 (2.00%)
Carbon Dioxide Decreased [*1]		
# participants affected / at risk	0/104 (0.00%)	2/100 (2.00%)
White Blood Cell Count Increased [*1]		
# participants affected / at risk	1/104 (0.96%)	3/100 (3.00%)
[*1]		

Hyperglycaemia		
# participants affected / at risk	**2/104 (1.92%)**	**3/100 (3.00%)**
Hypoglycaemia [*1]		
# participants affected / at risk	**1/104 (0.96%)**	**3/100 (3.00%)**
Hypokalaemia [*1]		
# participants affected / at risk	**2/104 (1.92%)**	**2/100 (2.00%)**
Musculoskeletal and connective tissue disorders		
Arthralgia [*1]		
# participants affected / at risk	**1/104 (0.96%)**	**3/100 (3.00%)**
Back Pain [*1]		
# participants affected / at risk	**1/104 (0.96%)**	**2/100 (2.00%)**
Nervous system disorders		
Convulsion [*1]		
# participants affected / at risk	**3/104 (2.88%)**	**0/100 (0.00%)**
Headache [*1]		
# participants affected / at risk	**5/104 (4.81%)**	**4/100 (4.00%)**
Psychiatric disorders		
Agitation [*1]		
# participants affected / at risk	**3/104 (2.88%)**	**3/100 (3.00%)**
Confusional State [*1]		
# participants affected / at risk	**3/104 (2.88%)**	**2/100 (2.00%)**
Delirium [*1]		
# participants affected / at risk	**0/104 (0.00%)**	**2/100 (2.00%)**
Depression [*1]		
# participants affected / at risk	**3/104 (2.88%)**	**1/100 (1.00%)**
Insomnia [*1]		
# participants affected / at risk	**3/104 (2.88%)**	**1/100 (1.00%)**
Renal and urinary disorders		
Renal Failure [*1]		
# participants affected / at risk	**3/104 (2.88%)**	**2/100 (2.00%)**
Renal Failure Acute [*1]		
# participants affected / at risk	**0/104 (0.00%)**	**2/100 (2.00%)**
Reproductive system and breast disorders		
Vaginal Discharge [*1]		
# participants affected / at risk	**3/104 (2.88%)**	**1/100 (1.00%)**
Respiratory, thoracic and mediastinal disorders		
Bronchospasm [*1]		
# participants affected / at risk	**1/104 (0.96%)**	**2/100 (2.00%)**
Dyspnoea [*1]		
# participants affected / at risk	**4/104 (3.85%)**	**3/100 (3.00%)**
Lung Infiltration [*1]		

# participants affected / at risk	0/104 (0.00%)	2/100 (2.00%)
Pleural Effusion * 1		
# participants affected / at risk	2/104 (1.92%)	2/100 (2.00%)
Pulmonary Embolism * 1		
# participants affected / at risk	0/104 (0.00%)	2/100 (2.00%)
Pulmonary Oedema * 1		
# participants affected / at risk	0/104 (0.00%)	2/100 (2.00%)
Tachypnoea * 1		
# participants affected / at risk	3/104 (2.88%)	1/100 (1.00%)
Skin and subcutaneous tissue disorders		
Decubitus Ulcer * 1		
# participants affected / at risk	3/104 (2.88%)	5/100 (5.00%)
Pruritus * 1		
# participants affected / at risk	0/104 (0.00%)	3/100 (3.00%)
Rash * 1		
# participants affected / at risk	5/104 (4.81%)	3/100 (3.00%)
Vascular disorders		
Haematoma * 1		
# participants affected / at risk	3/104 (2.88%)	0/100 (0.00%)
Hypertension * 1		
# participants affected / at risk	5/104 (4.81%)	6/100 (6.00%)
Hypotension * 1		
# participants affected / at risk	7/104 (6.73%)	3/100 (3.00%)
Jugular Vein Thrombosis * 1		
# participants affected / at risk	0/104 (0.00%)	2/100 (2.00%)
Phlebitis * 1		
# participants affected / at risk	3/104 (2.88%)	1/100 (1.00%)
Venous Thrombosis Limb * 1		
# participants affected / at risk	0/104 (0.00%)	3/100 (3.00%)

* Events were collected by non-systematic assessment

1 Term from vocabulary, MedDRA 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.

☑ **Restriction Description:** Merck agreements may vary with individual investigators, but will not prohibit any investigator from publishing. Merck supports the publication of results from all centers of a multi-center trial but requests that reports based on single-site data not precede the primary publication of the entire clinical trial.

Results Point of Contact:

Name/Title: Senior Vice President, Global Clinical Development
Organization: Merck Sharp & Dohme Corp
phone: 1-800-672-6372
e-mail: ClinicalTrialsDisclosure@merck.com

Publications:

Betts RF, Nucci M, Talwar D, Gareca M, Queiroz-Telles F, Bedimo RJ, Herbrecht R, Ruiz-Palacios G, Young JA, Baddley JW, Strohmaier KM, Tucker KA, Taylor AF, Kartsonis NA; Caspofungin High-Dose Study Group. A Multicenter, double-blind trial of a high-dose caspofungin treatment regimen versus a standard caspofungin treatment regimen for adult patients with invasive candidiasis. Clin Infect Dis. 2009 Jun 15;48(12):1676-84. doi: 10.1086/598933.

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00250432 History of Changes
Other Study ID Numbers:	0991-801 2005_085
Study First Received:	November 4, 2005
Results First Received:	January 13, 2009
Last Updated:	September 24, 2015
Health Authority:	United States: Food and Drug Administration

TO TOP

For Patients and Families | For Researchers | For Study Record Managers

HOME RSS FEEDS SITE MAP TERMS AND CONDITIONS DISCLAIMER CONTACT NLM HELP DESK