Clinical Trial to Study the Safety and Effectiveness of MK0826 and Other Antibiotic Therapy in Patients With Complicated Urinary Tract Infection (0826-054)

This study has been terminated.

(feasibility and low enrollment)

Sponsor:
Merck Sharp & Dohme Corp.

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

ClinicalTrials.gov Identifier:
NCT00771316

First received: October 9, 2008
Last updated: October 1, 2015
Last verified: October 2015
History of Changes

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Purpose

The purpose of this study is to demonstrate that MK0826 is comparable to Meropenem in the treatment of complicated Urinary Tract Infections (UTIs) in adults.

Condition	Intervention	Phase
Urinary Tract Infections	Drug: MK0826 (ertapenem) Drug: Comparator: meropenem	Phase 3

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

Official Title: A Phase 3, Randomized, Active Comparator-Controlled Clinical Trial to Study the Safety and Efficacy of MK0826 and Meropenem in Patients With Complicated Urinary Tract Infection

Resource links provided by NLM:

MedlinePlus related topics: Urinary Tract Infections

Drug Information available for: Meropenem Ertapenem sodium Ertapenem

U.S. FDA Resources

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

Primary Outcome Measures:

- Number of Participants With Serious Urinary Tract Infection With an Overall Microbiological Response to MK0826 Compared to Meropenem at the 5 to 9 Day Post Therapy Early Follow-up Visit [Time Frame: 5 to 9 days post therapy] [Designated as safety issue: No]

  Microbiological response defined as: 1) Eradication-urine culture shows reduced uropathogen, 2)Persistence-urine culture taken after at least 2 days of therapy grows the original uropathogen, 3)Persistence with Acquisition of Resistance- urine culture taken after at least 2 days of therapy grows the original uropathogen but shows resistance to study drug, 4)Superinfection-Growth of uropathogen other than original pathogen, 5)New Infection-A new pathogen grows other than the original uropathogen, 6)Indeterminate-Any circumstance where impossible to define microbiological response.

- Number of Participants With Serious Urinary Tract Infection With a Clinical Response to MK0826 Compared to Meropenem at Discontinuation of Intravenous Therapy (DCIV) [Time Frame: After at least 4 days of IV therapy] [Designated as safety issue: No]

  Clinical response at DCIV defined as: 1) Improved-All or most pretherapy signs and symptoms of infection have improved and no additional antibiotic is required, 2) Failure-No response to therapy, persistence or progression of pretherapy signs and symptoms, 3) Indeterminate-Study data not available due to complications related to underlying medical condition, patient withdrawn from study or extenuating circumstances preclude classification as improved or failure.

- Number of Participants With Serious Urinary Tract Infection With an Overall Microbiological Response to MK0826 Compared to Meropenem at Discontinuation of Intravenous Therapy (DCIV) [Time Frame: After at least 4 days of IV therapy] [Designated as safety issue: No]

  Microbiological response defined as: 1) Eradication-urine culture shows reduced uropathogen, 2)Persistence-urine culture taken after at least 2 days of therapy grows the original uropathogen, 3)Persistence with Acquisition of Resistance- urine culture taken after at least 2 days of therapy grows the original uropathogen but shows resistance to study drug, 4)Superinfection-Growth of uropathogen other than original pathogen, 5)New Infection-A new pathogen grows other than the original uropathogen, 6)Indeterminate-Any circumstance where impossible to define microbiological response.

Enrollment:	6
Study Start Date:	December 2008
Study Completion Date:	June 2009
Primary Completion Date:	June 2009 (Final data collection date for primary outcome measure)

Arms	Assigned Interventions
Experimental: Group 1 MK0826 (ertapenem)	Drug: MK0826 (ertapenem) A single dose of 1.0g IV infused over a 30 minute interval at hour 0
Active Comparator: Group 2 meropenem	Drug: Comparator: meropenem 500 mg IV infused over a 30 minute interval at hours 0, 8, and 16 for at least 4 days

Eligibility

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

Criteria

Inclusion Criteria:

- Patient has a clinically suspected and /or bacteriologically documented complicated UTI or acute pyelonephritis judged by the investigator to be serious
- Patient has one positive urine culture within 48 hours of enrollment
- Patient has one or more signs or symptoms of either upper or lower UTI
- Patient is male with or without a bladder catheter or urologic abnormalities; OR patient is a female with a history or clinical evidence of one or more urologic abnormalities

Exclusion Criteria:

- Patient has received any amount of effective concomitant antibiotic therapy after obtaining the urine culture for admission to this study (admission urine culture) and prior to the administration of the first dose of study antibiotics
- Patient's infection has been treated with greater than 24 hours of systemic antibiotic therapy known to be effective against the presumed or

documented pathogens within the 72 hour period immediately prior to consideration for entry into the study

- Patient has complete obstruction of any portion of the urinary tract. Patient has a history of seizures other than an uncomplicated febrile seizure

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: NCT00771316

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

Responsible Party:	Merck Sharp & Dohme Corp.
ClinicalTrials.gov Identifier:	NCT00771316 History of Changes
Other Study ID Numbers:	0826-054 MK0826-054 2008_562
Study First Received:	October 9, 2008
Results First Received:	April 22, 2010
Last Updated:	October 1, 2015
Health Authority:	United States: Food and Drug Administration

Additional relevant MeSH terms:

Infection	Anti-Bacterial Agents
Urinary Tract Infections	Anti-Infective Agents
Urologic Diseases	Pharmacologic Actions
Ertapenem	Therapeutic Uses
Meropenem	

ClinicalTrials.gov processed this record on April 14, 2016

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ClinicalTrials.gov Identifier:
NCT00771316

First received: October 9, 2008
Last updated: October 1, 2015
Last verified: October 2015
History of Changes

Results First Received: April 22, 2010

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Double Blind (Subject, Investigator); Primary Purpose: Treatment
Condition:	Urinary Tract Infections
Interventions:	Drug: MK0826 (ertapenem) Drug: Comparator: meropenem

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

Phase III

First patient enrolled on 09-Dec-2008

Last patient enrolled on 12-May-2009

The last patient's last visit was 08-Jun-2009

The study was conducted at 6 study centers in the United States and Europe.

Study was terminated early due to feasibility issues including slow enrollment.

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
MK0826 (Ertapenem)	MK0826-Patient received a once daily, intravenous infusion of 1.0g of MK0826 plus placebo (0.9% saline) at Hours 0, 8 and 16 for at least 4 days.
Meropenem	Meropenem-Patient received a once daily, intravenous infusion of 500 mg of meropenem at Hours 0, 8 and 16 for at least 4 days.

Participant Flow: Overall Study

	MK0826 (Ertapenem)	Meropenem
STARTED	4	2
COMPLETED	2	1
NOT COMPLETED	2	1
Adverse Event	0	1
Patient withdrew consent	1	0
Discontinued due to early termination	1	0

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
MK0826 (Ertapenem)	MK0826-Patient received a once daily, intravenous infusion of 1.0g of MK0826 plus placebo (0.9% saline) at Hours 0, 8 and 16 for at least 4 days.
Meropenem	Meropenem-Patient received a once daily, intravenous infusion of 500 mg of meropenem at Hours 0, 8 and 16 for at least 4 days.
Total	Total of all reporting groups

Baseline Measures

	MK0826 (Ertapenem)	Meropenem	Total
Number of Participants [units: participants]	4	2	6
Age [units: years]	37.75 (21 to 50)	58 (58 to 58)	44.5 (21 to 58)

Mean (Full Range)			
Gender [units: participants]			
Female	**2**	**0**	**2**
Male	**2**	**2**	**4**
Race/Ethnicity, Customized [units: participants]			
White	**4**	**2**	**6**

Outcome Measures

Hide All Outcome Measures

1. Primary: Number of Participants With Serious Urinary Tract Infection With an Overall Microbiological Response to MK0826 Compared to Meropenem at the 5 to 9 Day Post Therapy Early Follow-up Visit [Time Frame: 5 to 9 days post therapy]

Measure Type	Primary
Measure Title	Number of Participants With Serious Urinary Tract Infection With an Overall Microbiological Response to MK0826 Compared to Meropenem at the 5 to 9 Day Post Therapy Early Follow-up Visit
Measure Description	Microbiological response defined as: 1) Eradication-urine culture shows reduced uropathogen, 2)Persistence-urine culture taken after at least 2 days of therapy grows the original uropathogen, 3)Persistence with Acquisition of Resistance- urine culture taken after at least 2 days of therapy grows the original uropathogen but shows resistance to study drug, 4)Superinfection-Growth of uropathogen other than original pathogen, 5)New Infection-A new pathogen grows other than the original uropathogen, 6)Indeterminate-Any circumstance where impossible to define microbiological response.
Time Frame	5 to 9 days post 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.
This analysis was not completed due to early termination of the study.

Reporting Groups

	Description
MK0826 (Ertapenem)	MK0826-Patient received a once daily, intravenous infusion of 1.0g of MK0826 plus placebo (0.9% saline) at Hours 0, 8 and 16 for at least 4 days.
Meropenem	Meropenem-Patient received a once daily, intravenous infusion of 500 mg of meropenem at Hours 0, 8 and 16 for at least 4 days.

Measured Values

	MK0826 (Ertapenem)	**Meropenem**
Number of Participants Analyzed [units: participants]	**0**	**0**

Number of Participants With Serious Urinary Tract Infection With an Overall Microbiological Response to MK0826 Compared to Meropenem at the 5 to 9 Day Post Therapy Early Follow-up Visit		

No statistical analysis provided for Number of Participants With Serious Urinary Tract Infection With an Overall Microbiological Response to MK0826 Compared to Meropenem at the 5 to 9 Day Post Therapy Early Follow-up Visit

2. Primary: Number of Participants With Serious Urinary Tract Infection With a Clinical Response to MK0826 Compared to Meropenem at Discontinuation of Intravenous Therapy (DCIV) [Time Frame: After at least 4 days of IV therapy]

Measure Type	Primary
Measure Title	Number of Participants With Serious Urinary Tract Infection With a Clinical Response to MK0826 Compared to Meropenem at Discontinuation of Intravenous Therapy (DCIV)
Measure Description	Clinical response at DCIV defined as: 1) Improved-All or most pretherapy signs and symptoms of infection have improved and no additional antibiotic is required, 2) Failure-No response to therapy, persistence or progression of pretherapy signs and symptoms, 3) Indeterminate-Study data not available due to complications related to underlying medical condition, patient withdrawn from study or extenuating circumstances preclude classification as improved or failure.
Time Frame	After at least 4 days 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.
This analysis was not completed due to early termination of the study.

Reporting Groups

	Description
MK0826 (Ertapenem)	MK0826-Patient received a once daily, intravenous infusion of 1.0g of MK0826 plus placebo (0.9% saline) at Hours 0, 8 and 16 for at least 4 days.
Meropenem	Meropenem-Patient received a once daily, intravenous infusion of 500 mg of meropenem at Hours 0, 8 and 16 for at least 4 days.

Measured Values

	MK0826 (Ertapenem)	**Meropenem**
Number of Participants Analyzed [units: participants]	**0**	**0**
Number of Participants With Serious Urinary Tract Infection With a Clinical Response to MK0826 Compared to Meropenem at Discontinuation of Intravenous Therapy (DCIV)		

No statistical analysis provided for Number of Participants With Serious Urinary Tract Infection With a Clinical Response to MK0826 Compared to Meropenem at Discontinuation of Intravenous Therapy (DCIV)

3. Primary: Number of Participants With Serious Urinary Tract Infection With an Overall Microbiological Response to MK0826 Compared to Meropenem at Discontinuation of Intravenous Therapy (DCIV) [Time Frame: After at least 4 days of IV therapy]

Measure Type	Primary
Measure Title	Number of Participants With Serious Urinary Tract Infection With an Overall Microbiological Response to MK0826 Compared to Meropenem at Discontinuation of Intravenous Therapy (DCIV)
Measure Description	Microbiological response defined as: 1) Eradication-urine culture shows reduced uropathogen, 2)Persistence-urine culture taken after at least 2 days of therapy grows the original uropathogen, 3)Persistence with Acquisition of Resistance- urine culture taken after at least 2 days of therapy grows the original uropathogen but shows resistance to study drug, 4)Superinfection-Growth of uropathogen other than original pathogen, 5)New Infection-A new pathogen grows other than the original uropathogen, 6)Indeterminate-Any circumstance where impossible to define microbiological response.
Time Frame	After at least 4 days 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.
This analysis was not completed due to early termination of the study.

Reporting Groups

	Description
MK0826 (Ertapenem)	MK0826-Patient received a once daily, intravenous infusion of 1.0g of MK0826 plus placebo (0.9% saline) at Hours 0, 8 and 16 for at least 4 days.
Meropenem	Meropenem-Patient received a once daily, intravenous infusion of 500 mg of meropenem at Hours 0, 8 and 16 for at least 4 days.

Measured Values

	MK0826 (Ertapenem)	**Meropenem**
Number of Participants Analyzed [units: participants]	**0**	**0**
Number of Participants With Serious Urinary Tract Infection With an Overall Microbiological Response to MK0826 Compared to Meropenem at Discontinuation of Intravenous Therapy (DCIV)		

No statistical analysis provided for Number of Participants With Serious Urinary Tract Infection With an Overall Microbiological Response to MK0826 Compared to Meropenem at Discontinuation of Intravenous Therapy (DCIV)

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	Any serious adverse experience, including death due to any cause, which occurred to any subject entered in the study or within 14 days following cessation of treatment.
Additional Description	No text entered.

Reporting Groups

	Description
MK0826 (Ertapenem)	MK0826-Patient received a once daily, intravenous infusion of 1.0g of MK0826 plus placebo (0.9% saline) at Hours 0, 8

	and 16 for at least 4 days.
Meropenem	Meropenem-Patient received a once daily, intravenous infusion of 500 mg of meropenem at Hours 0, 8 and 16 for at least 4 days.

Serious Adverse Events

	MK0826 (Ertapenem)	Meropenem
Total, serious adverse events		
# participants affected / at risk	**0/4 (0.00%)**	**1/2 (50.00%)**
General disorders		
Shortness of breath * 1		
# participants affected / at risk	**0/4 (0.00%)**	**1/2 (50.00%)**
Chest pain * 1		
# participants affected / at risk	**0/4 (0.00%)**	**1/2 (50.00%)**

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

Other Adverse Events

Hide Other Adverse Events

Time Frame	Any serious adverse experience, including death due to any cause, which occurred to any subject entered in the study or within 14 days following cessation of treatment.
Additional Description	No text entered.

Frequency Threshold

Threshold above which other adverse events are reported	0%

Reporting Groups

	Description
MK0826 (Ertapenem)	MK0826-Patient received a once daily, intravenous infusion of 1.0g of MK0826 plus placebo (0.9% saline) at Hours 0, 8 and 16 for at least 4 days.
Meropenem	Meropenem-Patient received a once daily, intravenous infusion of 500 mg of meropenem at Hours 0, 8 and 16 for at least 4 days.

Other Adverse Events

	MK0826 (Ertapenem)	Meropenem
Total, other (not including serious) adverse events		
# participants affected / at risk	**1/4 (25.00%)**	**0/2 (0.00%)**
Gastrointestinal disorders		

Mouth dryness * 1		
# participants affected / at risk	1/4 (25.00%)	0/2 (0.00%)

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

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

The reason for early termination: Study was terminated early due to feasibility issues including slow enrollment.

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: Vice President, Late Stage Development Group Leader
Organization: Merck Sharp & Dohme Corp.
phone: 1-800-672-6372
e-mail: ClinicalTrialsDisclosure@merck.com

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