# Ertapenem versus Ceftriaxone and Metronidazole As Treatment For Complicated Intra-abdominal Infections

Submission date	Recruitment status	Prospectively registered		
14/01/2005	No longer recruiting	☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
19/01/2005	Completed	[X] Results		
Last Edited	Condition category	Individual participant data		
13/08/2009	Infections and Infestations			

# Plain English summary of protocol

Not provided at time of registration

# Contact information

# Type(s)

Scientific

#### Contact name

Dr Christina Y. Chan

#### Contact details

Merck & Co., Inc. One Merck Drive Whitehouse Station United States of America 08889-0100

# Additional identifiers

**EudraCT/CTIS** number

**IRAS** number

 ${\bf Clinical Trials. gov\ number}$ 

Secondary identifying numbers

MK-0826 Protocol 802

# Study information

#### Scientific Title

A Prospective, Multicenter, Open-Label, Randomized, Comparative Study to Evaluate the Efficacy, Safety, and Tolerability of Ertapenem Versus Ceftriaxone/Metronidazole in the Treatment of Intra-Abdominal Infections in Adults

#### Acronym

**OASIS II** 

#### **Study objectives**

Not provided at time of registration

As of 13/08/09 this record has been extensively updated. All updates can be found in the relevant field with the above update date. Please also note that the country of recruitment has been corrected, initially USA was entered in error.

#### Ethics approval required

Old ethics approval format

#### Ethics approval(s)

Not provided at time of registration

## Study design

Multicentre randomised open label active controlled parallel group trial

# Primary study design

Interventional

# Secondary study design

Randomised controlled trial

# Study setting(s)

Not specified

# Study type(s)

**Not Specified** 

#### Participant information sheet

# Health condition(s) or problem(s) studied

Complicated intra-abdominal infections

#### **Interventions**

Current information as of 13/08/09:

Adult patients with intra-abdominal infections requiring surgery were eligible for this open-label randomized trial comparing ertapenem 1 g daily with ceftriaxone 2 g daily plus metronidazole 30 mg/kg/day.

Initial information at time of registration: Ertapenem, ceftriaxone, metronidazole

#### Intervention Type

Drug

#### Phase

**Not Specified** 

## Drug/device/biological/vaccine name(s)

Ertapenem, ceftriaxone, metronidazole

#### Primary outcome measure

Added 13/08/09:

Efficacy as measured by clinical response rate in clinically and microbiologically evaluable participants at the test-of-cure (TOC) visit 2 weeks after discontinuation of therapy

#### Secondary outcome measures

Added 13/08/09:

Efficacy measured at TOC visit 4 weeks after discontinuation of therapy

#### Overall study start date

01/06/2002

#### Completion date

30/06/2003

# Eligibility

#### Key inclusion criteria

Current information as of 13/08/09:

- 1. Male or female patients aged 18 or over
- 2. Patient has a diagnosis of intra-abdominal infection requiring surgery as evidenced by fever, elevated while blood cell count and abdominal pain

Initial information at time of registration:

Adult patients with intra-abdominal infections requiring surgery

#### Participant type(s)

**Patient** 

#### Age group

Adult

#### Lower age limit

18 Years

#### Sex

Both

# Target number of participants

500

#### Key exclusion criteria

Added 13/08/09:

- 1. Patient has another infection, other than abdominal
- 2. Female patient is pregnant or planning to become pregnant

#### Date of first enrolment

01/06/2002

#### Date of final enrolment

30/06/2003

# Locations

#### Countries of recruitment

**Philippines** 

United States of America

# Study participating centre

Merck & Co., Inc.

Whitehouse Station United States of America 08889-0100

# Sponsor information

# Organisation

Merck and Co., Inc. (USA)

# Sponsor details

Christina Y. Chan, M.D. One Merck Drive Whitehouse Station United States of America 08889-0100

## Sponsor type

Industry

# Funder(s)

## Funder type

Industry

#### **Funder Name**

Merck & Co., Inc. (USA)

## Alternative Name(s)

Merck & Co., Inc., Merck & Co.

#### **Funding Body Type**

Government organisation

## Funding Body Subtype

For-profit companies (industry)

#### Location

United States of America

# **Results and Publications**

# Publication and dissemination plan

Not provided at time of registration

#### Intention to publish date

Individual participant data (IPD) sharing plan

# IPD sharing plan summary

Not provided at time of registration

## **Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	01/02/2005		Yes	No