

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

Submission date
14/01/2005

Recruitment status
No longer recruiting

☐ Prospectively registered

☐ Protocol

Registration date
19/01/2005

Overall study status
Completed

☐ Statistical analysis plan

☒ Results

Last Edited
13/08/2009

Condition category
Infections and Infestations

☐ Individual participant data

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Contact details

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

Additional identifiers

Protocol serial number

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

Primary study design

Interventional

Study design

Multicentre randomised open label active controlled parallel group trial

Study type(s)

Not Specified

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(s)

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

Key secondary outcome(s)

Added 13/08/09:

Efficacy measured at TOC visit 4 weeks after discontinuation of therapy

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 white blood cell count and abdominal pain

Initial information at time of registration:

Adult patients with intra-abdominal infections requiring surgery

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

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)

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

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