ISRCTN59616541 https://doi.org/10.1186/ISRCTN59616541

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

ClinicalTrials.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