A Multicenter, Prospective, Observational Study Investigating Clinical Outcomes Associated with Antimicrobial Therapy among Chinese Patients with Complicated Intraabdominal Infections in the Real-World Clinical Practice

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Study Planned

Administrative details

PURI

https://redirect.ema.europa.eu/resource/42203

EU PAS number

EUPAS42202

Study ID

42203

DARWIN EU® study

No

Study countries

☐ China

Study description

Antimicrobial resistance has increasingly been seen in cIAIs worldwide including China. But there have been limited studies to generate real-world evidence on clinical outcomes associated with antimicrobial therapy and microbiology profiles in Chinese patients with cIAIs. The study was designed to investigate the rate of favourable clinical response to antimicrobial therapy at the clinical evaluation in Chinese patients who have cIAIs and are clinically evaluable (CE). The study is a multicenter, prospective, observational study with descriptive analyses on one single patient cohort. Chinese patients with cIAIs requiring hospitalization for surgical interventions and antimicrobial therapy will be enrolled in a period of approximately 18 months.

Study status

Planned

Research institutions and networks

Institutions

Shanghai Jiao Tong University School of Medicine - Xinhua Hospital

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Institution

Contact details

Study institution contact

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Study contact

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Primary lead investigator

Zhiwei Quan

Primary lead investigator

Study timelines

Date when funding contract was signed
Planned: 26/08/2021

Study start date
Planned: 02/09/2021

Data analysis start date
Planned: 14/03/2003

Date of final study report
Planned: 25/08/2023

Sources of funding

- Pharmaceutical company and other private sector

More details on funding

Merck Sharp & Dohme

Regulatory

Was the study required by a regulatory body?

No

Is the study required by a Risk Management Plan (RMP)?

Not applicable

Methodological aspects

Study type

Study type list

Study type:

Non-interventional study

Scope of the study:

Effectiveness study (incl. comparative)

Main study objective:

To investigate the rate of favourable clinical response to antimicrobial therapy at the clinical evaluation in Chinese patients who have cIAIs and are clinically

evaluable (CE).

Study Design

Non-interventional study design

Cohort

Study drug and medical condition

Anatomical Therapeutic Chemical (ATC) code

(J01DH) Carbapenems

Carbapenems

(J01DI) Other cephalosporins and penems

Other cephalosporins and penems

Medical condition to be studied

Abdominal infection

Gastrointestinal infection

Population studied

Age groups

Adults (18 to < 46 years)

Adults (46 to < 65 years)

Adults (65 to < 75 years)

Adults (75 to < 85 years)

Adults (85 years and over)

Estimated number of subjects

980

Study design details

Outcomes

Favourable clinical response to antimicrobial therapy at the clinical evaluation in Chinese patients who have cIAIs and are clinically evaluable (CE), 1. Favourable clinical response to antimicrobial therapy at the clinical evaluation in ME, 2. Favourable clinical response to antimicrobial therapy at the end of antibiotic course 3. Appropriateness of empiric antimicrobial therapy, 4. Hospital readmission at the late clinical evaluation, 5. Clinical characteristics associated with favourable clinical response to antimicrobial therapy.

Data analysis plan

Descriptive statistics by point estimate with Wilson score 95% CIs, multivariate logistic regression to identify predictors associated with treatment success.

Data management

Data sources

Data sources (types)

Other

Data sources (types), other

Prospective patient-based data collection

Use of a Common Data Model (CDM)

CDM mapping

No

Data quality specifications

Check conformance

Unknown

Check completeness

Unknown

Check stability

Unknown

Check logical consistency

Unknown

Data characterisation

Data characterisation conducted

No