

# 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

### EU PAS number

EUPAS42202

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### Study ID

42203

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### DARWIN EU® study

No

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### Study countries

## Study description

Antimicrobial resistance has increasingly been seen in cIAls 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 cIAls. The study was designed to investigate the rate of favourable clinical response to antimicrobial therapy at the clinical evaluation in Chinese patients who have cIAls and are clinically evaluable (CE). The study is a multicenter, prospective, observational study with descriptive analyses on one single patient cohort. Chinese patients with cIAls requiring hospitalization for surgical interventions and antimicrobial therapy will be enrolled in a period of approximately 18 months.

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## 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

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### **Study start date**

Planned: 02/09/2021

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### **Data analysis start date**

Planned: 14/03/2003

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### **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

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

Not applicable

## Methodological aspects

### Study type

### Study type list

#### **Study type:**

Non-interventional study

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#### **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 cIAls 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

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### **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)
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### **Estimated number of subjects**

980

## Study design details

## Outcomes

Favourable clinical response to antimicrobial therapy at the clinical evaluation in Chinese patients who have cIAls 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.

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## 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

### ENCePP Seal

The use of the ENCePP Seal has been discontinued since February 2025. The ENCePP Seal fields are retained in the display mode for transparency but are no longer maintained.

## Data sources

### Data sources (types)

[Other](#)

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### 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

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### **Check completeness**

Unknown

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### **Check stability**

Unknown

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### **Check logical consistency**

Unknown

## Data characterisation

### **Data characterisation conducted**

No