

# Effects of Jinghuaweikang capsule combined quadruple therapy on the refractory infection of *Helicobacter pylori*

<b>Submission date</b> 22/04/2018	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 09/05/2018	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 01/09/2021	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

*Helicobacter pylori* infects approximately 50% of the adult population and is associated with a wide range of diseases. Because of antibiotic resistance, failure to eradicate (remove) *Helicobacter pylori* is becoming a common and challenging problem.

This study aims to see whether Jinghuaweikang capsule combined quadruple therapy might help those with refractory *Helicobacter pylori* infection. Previous studies have suggested a benefit but this needs confirmation.

### Who can participate?

Adults aged 18 – 65 years with refractory *Helicobacter pylori* infection.

### What does the study involve?

Participants are randomly allocated to one of three groups, to take a different combination of medication, as follows:

1. Rabeprazole 20 mg Bid and Bismuth potassium citrate 220mg Bid and amoxicillin 1 g Bid and furazolidone 0.1g Bid for 14 days
2. Rabeprazole 20 mg Bid and Bismuth potassium citrate 220mg Bid and amoxicillin 1 g Bid and furazolidone 0.1g Bid for 10 days and Jinghuaweikang capsule 160mg Tid for 14 days
3. Rabeprazole 20 mg Bid and Jinghuaweikang capsule 160mg Tid and amoxicillin 1 g Bid and furazolidone 0.1g Bid for 10 days and Jinghuaweikang capsule 160mg Tid for 14 days

Participants are followed up 56 days after starting their medication.

### What are the possible benefits and risks of participating?

It is hoped that the *Helicobacter pylori* infection will be eradicated. The drugs have been used for many years and the side effects are well recognised. Only very few participants may not tolerate the drug because of stomach discomfort, dryness of the mouth, constipation, diarrhoea, nausea, rash or dizziness.

Where is the study run from?

1. Peking University First Hospital (China)
2. Beijing Hospital of Traditional Chinese Medicine Affiliated to Capital Medical University (China)
3. PLA Army General Hospital (China)
4. Dongfang Hospital Beijing University of Chinese Medicine (China)
5. Guanganmen Hospital China Academy of Chinese Medical Sciences (China)
6. Aerospace Center Hospital (China)
7. Xijing Hospital of the Fourth Military Medical University (China)
8. China-Japan Union Hospital of Jinlin University (China)
9. Shengjing Hospital of China Medical University (China)
10. Nanfang Hospital of Southern Medical University (China)
11. Tongji Hospital of Tongji Medical College, Huazhong University of Science and Technology (China)
12. The First Affiliated Hospital of Nanjing Medical University, Jiangsu Province Hospital (China)
13. The Second Affiliated Hospital of Xian Jiaotong University (China)
14. Qilu Hospital of Shandong University (China)
15. The Fifth Affiliated Hospital of Zhengzhou University (China)
16. Changhai Hospital, Second Military Medical University (China)

When is the study starting and how long is it expected to run for?

March 2018 to December 2022 (updated 01/09/2021, previously: December 2021)

Who is funding the study?

Tasly Pharmaceutical Group CO.,LTD (China)

Who is the main contact?

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## Contact information

### Type(s)

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### Contact name

Dr Shengsheng Zhang

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**Additional identifiers**

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

2018-03-20

**Study information****Scientific Title**

Randomised multicentric controlled clinical trial to compare efficacy of Jinghuaweikang capsule combined quadruple therapy versus quadruple therapy on the refractory infection of *Helicobacter pylori*

**Study objectives**

Jinghuaweikang capsule combined quadruple therapy is better than quadruple therapy

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

Ethics Committee of Peking University First Hospital, 28/03/2018, ref: 2018-34

**Study design**

Multi-centre randomised parallel controlled trial

**Primary study design**

Interventional

**Secondary study design**

Randomised parallel trial

**Study setting(s)**

Hospital

**Study type(s)**

## Treatment

### Participant information sheet

No participant information sheet available

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

Helicobacter pylori

### Interventions

Participants are randomly allocated to one of three options of therapy:

1. Rabeprazole 20 mg Bid and Bismuth potassium citrate 220mg Bid and amoxicillin 1g Bid and furazolidone 0.1g Bid for 14 days
2. Rabeprazole 20 mg Bid and Bismuth potassium citrate 220mg Bid and amoxicillin 1g Bid and furazolidone 0.1g Bid for 10 days and Jinghuaweikang capsule 160mg Tid for 14 days
3. Rabeprazole 20 mg Bid and Jinghuaweikang capsule 160mg Tid and amoxicillin 1g Bid and furazolidone 0.1g Bid for 10 days and Jinghuaweikang capsule 160mg Tid for 14 days

The duration of follow up was 56 days after medications started.

### Intervention Type

Drug

### Phase

Not Specified

### Primary outcome measure

Elimination rate of Helicobacter pylori is measured using 13C-urea breath test at 56 days

### Secondary outcome measures

Gastrointestinal symptoms are measured using Scale of gastrointestinal symptoms at baseline, 14 days, 28 days and 56 days

### Overall study start date

01/03/2018

### Completion date

31/12/2022

## Eligibility

### Key inclusion criteria

1. Aged 18 to 65 without gender limitation.
2. Meet the refractory Helicobacter pylori infection:
  - 2.1. Referred after three or more than three standard therapy (according to consensus for 10-14 days, at least two times of standard quadruple therapy, at least one time for 14 days) failures in three years.
  - 2.2. Received upper endoscopy and suitable for eradication of Helicobacter pylori.
3. Diagnosed with Helicobacter pylori infection by rapid urease test or 13C-urea breath test results.
4. Proven endoscopic gastritis (including atrophic gastritis and non-atrophic gastritis) or ulcers.

5. Participants without prior penicillin treatment need to demonstrate negative reaction to penicillin skin test.
6. No dyspepsia syndromes of epigastric discomfort, epigastric pain, acid regurgitation, heartburn, and so on, but meet indication of Helicobacter pylori eradication.
7. Accept the medications treatment voluntarily and signed informed consent.

**Participant type(s)**

Patient

**Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

510

**Key exclusion criteria**

1. History of stomach operation: partial gastrectomy, stomach plasty, vagotomy (but patients who had simple repair of gastroduodenal ulcer perforation or hemostatic suture of gastroduodenal ulcer were accepted)
2. Pregnancy or lactation, or childbearing age women without reliable contraception (e.g., oophorectomy, hysterectomy, at least 6 months of tubal ligation, oral contraceptives, barrier method of contraception)
3. Cannot avoid alcohol during the experiment
- 4 Patients who concomitant with liver disease, kidney disease, cardiovascular disease, brain disease, pulmonary disease, endocrine system diseases, hematopoietic system disease, and other serious primary diseases which is not effectively controlled
5. Severe hepatic and renal insufficiency( transaminase is more than 1.5 times of the normal limit, or serum creatinine more than the upper limit of normal )or liver disease, anemia (hemoglobin < 90 g/L)
6. Allergic to furazolidone, penicillin, rabeprazole or ingredients of JinghuaWeikang Capsule
7. Used antibiotics, bismuth agent (>three timesper week) or clinical trial other drugs within 30 days
- 8 . Taking anticoagulant therapy or non-steroidal anti-inflammatory drugs (NSAIDs)
9. Swallowing difficulties
10. Used anti-ulcer drugs, including H2-receptor blocking agent, sucralfate, misoprostol or proton pump inhibitor (PPI) within two weeks
11. Zollinger-Ellison syndrome
12. Malignant tumor
13. Included in another clinical trial within 3 months
14. Inappropriate according to the investigator

**Date of first enrolment**

01/08/2018

**Date of final enrolment**

31/07/2022

## **Locations**

### **Countries of recruitment**

China

### **Study participating centre**

**Peking University First Hospital**

China

100034

### **Study participating centre**

**Beijing Hospital of Traditional Chinese Medicine Affiliated to Capital Medical University**

China

100010

### **Study participating centre**

**PLA Army General Hospital**

China

100700

### **Study participating centre**

**Guanganmen Hospital, China Academy of Chinese Medical Sciences**

China

100053

### **Study participating centre**

**Aerospace Center Hospital, Peking university**

China

100049

### **Study participating centre**

**China-Japan Union Hospital of Jinlin University**

China

130033

**Study participating centre**  
**Shengjing Hospital of China Medical University**  
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**Tongji Hospital of Tongji Medical College, Huazhong University of Science and Technology**  
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430030

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**The First Affiliated Hospital of Nanjing Medical University, Jiangsu Province Hospital**  
China  
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**The Second Affiliated Hospital of Xian Jiaotong University**  
China  
710004

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**The Fifth Affiliated Hospital of Zhengzhou University**  
China  
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**Study participating centre**  
**Tianjin Medical University General Hospital**  
Tianjin  
China  
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**Study participating centre**

**The Third Xiangya Hospital of Central South University (China)**

China  
410205

**Study participating centre**

**Nanjing First Hospital (China)**

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## **Sponsor information**

**Organisation**

China Health Promotion Foundation

**Sponsor details**

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**Sponsor type**

Charity

## **Funder(s)**

**Funder type**

Industry

**Funder Name**

Tasly Pharmaceutical Group CO.,LTD (China).

## **Results and Publications**

**Publication and dissemination plan**

Planned publication in a high impact peer reviewed journal.

**Intention to publish date**

30/06/2023



**Individual participant data (IPD) sharing plan**

The data sharing plans for the current study are unknown and will be made available at a later date.

**IPD sharing plan summary**

Data sharing statement to be made available at a later date