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

Submission date
22/04/2018

Recruitment status
No longer recruiting

Registration date
09/05/2018

Overall study status
Completed

Last Edited
01/09/2021

Condition category
Infections and Infestations

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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?
1. Dr. Fulian Hu (Public)
djjyhu@163.com
2. Dr.Shengsheng Zhang (Public)
zhss2000@163.com

Contact information

Type(s)
Public

Contact name
Dr Fulian Hu

Contact details
Peking University First Hospital
No.8 xishu street
Xicheng district
Beijing
China
100034

Type(s)
Public

Contact name

Dr Shengsheng Zhang

Contact details
Beijing Hospital of Traditional Chinese Medicine Affiliated to Capital Medical University
No.23 Meishuguanhou Street
Dongcheng District
Beijing
China
100010

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
China
110004

Study participating centre
Nanfang Hospital of Southern Medical University
China
510515

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

Study participating centre
The First Affiliated Hospital of Nanjing Medical University, Jiangsu Province Hospital
China
210029

Study participating centre
The Second Affiliated Hospital of Xian Jiaotong University
China
710004

Study participating centre
The Fifth Affiliated Hospital of Zhengzhou University
China
450052

Study participating centre
Tianjin Medical University General Hospital
Tianjin
China
300052

Study participating centre

The Third Xiangya Hospital of Central South University (China)
China
410205

Study participating centre
Nanjing First Hospital (China)
China
210000

Sponsor information

Organisation
China Health Promotion Foundation

Sponsor details
No.316 Wanfeng Road
FengTai District
Beijing
China
100161

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