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Efficacy of Woxuan Needling and Xiangsha Liujunzi Decoction in Helicobacter pylori-positive chronic gastritis

Submission date 28/07/2026	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 14/08/2026	**Overall study status** Completed	
Last Edited 12/08/2026	**Condition category** Digestive System	

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Principal investigator, Public, Scientific

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Study information

Scientific Title
Efficacy of Woxuan needling and Xiangsha Liujunzi decoction on traditional Chinese medicine syndromes and gastric biomarkers in Helicobacter pylori-positive chronic gastritis

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 26/04/2021, Ethics Committee of Jiangxi Province Hospital of Integrated Chinese and Western Medicine (No. 1399 Diezihu Avenue, Honggutan District, Nanchang, 330003, China; +86 (0)791-86391701; nc2yhlb@163.com), ref: No. Yanlunwenpi [003]

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Blinded (masking used)

Control
Active

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Chronic non-atrophic gastritis in patients with Helicobacter pylori infection

Interventions
Participants are divided into an observation group and a control group using a random number table according to the order of enrolment.

The control group receives basic drug treatment combined with Xiangsha Liujunzi decoction, whereas the observation group receives Woxuan needling in addition to the control treatment.

The conventional Western medicine treatment plan is based on the Chinese Chronic Gastritis Diagnosis and Treatment Guide, which includes standard quadruple therapy. The specific medications are as follows: amoxicillin capsules (1 g) orally twice daily; furazolidone tablets (0.1 g) orally twice daily; 240 mg of bismuth potassium citrate (calculated as bismuth oxide) orally twice daily; and omeprazole enteric-coated capsules (20 mg) orally twice daily. These drugs are taken for 14 days.

As a routine basic treatment, Xiangsha Liujunzi decoction is used. The prescription is as follows: 12 g of Dangshen, 12 g of Fuling, 12 g of Baizhu, 12 g of Chenpi, 12 g of Fabanxia, 6 g of Zhigancao, 8 g of Muxiang and 8 g of A. villosum (Houxia). One dose per day is decocted twice, yielding approximately 250 ml of juice, taken twice daily in the morning and evening. Treatment is administered continuously for 6 days, followed by a 1-day rest interval, for a total treatment duration of 2 months.

On the basis of the treatment protocol of the control group, Woxuan needling is applied. The following acupoints are selected: Xinmen (right), Zusanli (right), Taichong (left), and Taibai (left). After skin disinfection, a 0.20 × 40 mm filiform needle is inserted. According to the acupuncture order of Woxuan needling, the following sequence is used: right heart door, right Zusanli, left Taichong, and left Taibai, quickly penetrating the skin in turn. During acupuncture, the needle tips at the right heart door and right Zusanli are directed downwards towards the distal end of the limb, whereas those at the left Taibai and left Taichong are directed upwards. After deqi, the right heart door and right Zusanli are gently twisted 5 times, and the left Taibai and left Taichong are twisted 10 times. The needles are retained for 30 minutes, during which the patients are required to close their eyes, breathe gently, keep their limbs warm, and remain comfortable. The procedure is performed three times a week for a total of 2 months.

The general data of patients, TCM symptom scores, pepsinogen I (PGI), GAS, gastroscopy scores and gastrointestinal symptom rating scale (GSRS) scores are collected before treatment and 3 months after treatment. The evaluators who assess the indices receive standardised training before evaluation, and the grouping of participants is not disclosed to them.

Intervention Type
Mixed

Primary outcome(s)
1. Chronic non-atrophic gastritis symptoms measured using TCM symptom scores at baseline and 3 months

2. Serum pepsinogen I (PGI) level measured using serum testing at baseline and 3 months

3. Gastrin (GAS) level measured using serum testing at baseline and 3 months

4. Gastroscopy score measured using gastric mucosal erythema features (3 points = extensive fusion; 2 points = dense spots or continuous linear blood; 1 point = scattered or intermittent linear congestion; 0 points = normal gastric mucosa) at baseline and 3 months

5. Gastrointestinal symptom severity measured using the Gastrointestinal Symptom Rating Scale (GSRS) at baseline and 3 months

Key secondary outcome(s)

Completion date
01/01/2023

Eligibility

Key inclusion criteria
1. Aged >18 years
2. Diagnosis consistent with the above diagnostic criteria for chronic non-atrophic gastritis
3. H. pylori positive

Healthy volunteers allowed
No

Age group
Mixed

Lower age limit
18 Years

Upper age limit
70 Years

Sex
All

Total final enrolment
120

Key exclusion criteria
1. Suspected or diagnosed malignant lesions combined with severe dysplasia of gastric mucosa
2. Combined with haematological diseases or abnormal coagulation function
3. Needle phobia
4. Lactating or pregnant women
5. Complicated with severe primary diseases of the brain, heart, liver, kidney or other major organs or a history of mental illness
6. Combined with malignant tumour
7. Allergic to TCM ingredients used in this study

Date of first enrolment
01/01/2022

Date of final enrolment
01/09/2022

Locations

Countries of recruitment
China

Sponsor information

Organisation
Jiangxi Province Hospital of Integrated Chinese and Western Medicine

Funder(s)

Funder type

Funder Name
Jiangxi Province Hospital of Integrated Chinese and Western Medicine

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available