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Efficacy and safety of Hou Gu Mi Xi rice paste on improving the symptoms of indigestion

Submission date
30/06/2022

Recruitment status
No longer recruiting

Registration date
06/07/2022

Overall study status
Completed

Last Edited
08/03/2024

Condition category
Digestive System

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Functional dyspepsia (FD), a kind of chronic indigestion, is defined by symptoms that are centered in the upper abdomen (the gastroduodenal region) without any underlying disease that might explain these symptoms. Jiangzhong Hou Gu Mi Xi® (HGMX) rice paste, a dietary traditional Chinese medicine (TCM) formula, is modified from the classic TCM Shen Ling Bai Zhu San formula. This study aims to explore the efficacy and safety of HGMX rice paste on the clinical symptoms of FD and to put forward some suggestions on dietary therapy with HGMX rice paste.

Who can participate?
Adults with FD

What does the study involve?
Participants are given health education and guidance on the use, dose, and precautions to take when consuming the rice paste. Rice paste is distributed at the beginning of the first month. Without affecting their normal diet, the participants will consume either one complete packet (30g) per day of HGMX or one complete packet (30g) per day of a dummy (placebo) product for 2 months under the supervision of the researcher's WeChat. Using WeChat, participants are asked to answer questions about their FD symptoms and quality of life, and other physical measurement indicators on the 15th, 30th, and 60th days after treatment, and at follow-up at 1 month after the expiration of the intervention. Participants are also asked for feedback and their feelings about the entire trial. The reasons for dropouts or withdrawals of participants are recorded in the case report form there is monitoring for any adverse events (AEs) and severe AEs (SAEs) throughout the entire trial period using a standard adverse event case report form.

What are the possible benefits and risks of participating?
Participants will benefit from HGMX and may get some compensation. There are risks associated with drawing blood.

Where is the study run from?
Beijing Shijitan Hospital, Capital Medical University (China)

When is the study starting and how long is it expected to run for?
January 2019 to April 2023

Who is funding the study?
Chinese Institute of Food Science and Technology, Food Science and Technology Fund (China)

Who is the main contact?
Dr Xin Wang (China)
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Contact information

Type(s)
Principal investigator

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Additional identifiers

Study information

Scientific Title
Efficacy and Safety of Hou Gu Mi Xi Rice Paste on Improving the Symptoms of Functional Dyspepsia: A Randomized, Placebo-Controlled, Clinical Trial

Study objectives
Hou Gu Mi Xi rice paste will provide an effective and safe method to improve the symptoms and quality of life in patients with functional dyspepsia

Ethics approval required
Old ethics approval format

Ethics approval(s)

Approved 26/05/2022, Clinical Research Ethics Committee of Beijing Shijitan Hospital (10 Tieyi Road, Yangfangdian Haidian District, Beijing, China; +86 (0)10 63926603; sjtkyll@126.com), ref: sjtkyll-lx-2020 (1)

Study design
Single-center single-dose prospective randomized controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Functional dyspepsia

Interventions
Before starting the intervention, researchers will provide health education to the subjects and give face-to-face guidance on the usage, dosage, and precautions of rice paste. Rice paste will be distributed at the beginning of the first month. Without affecting the normal diet, subjects would complete either one packet (30g) /day HGMX or one packet (30g)/day placebo, taken orally for a 2-month intervention under the supervision of the researcher's WeChat. Participants attend investigations, including global overall symptom scale (GOSS), 36-Item Short Form Survey (SF-36), body mass index (BMI), and other physical measurement indicators on the 15th, 30th, and 60th days after treatment, and follow-up at 1 month after the expiration of the intervention including GOSS, SF-36, BMI, other physical measurement indicators, feedback, and feelings about the entire trial. The form of the questionnaire is a WeChat answer sheet. Participants do not need to come to the hospital to complete the investigation at the time points except for baseline investigation. At the end of the test, it is necessary to take pictures of the remaining packaging bags of rice paste for two months to understand the completion of the test. The reasons for dropouts or withdrawals of participants would be recorded in the case report form. We will monitor any adverse events (AEs) and severe AEs (SAEs) throughout the entire trial period using a standard adverse event case report form.

Intervention Type
Supplement

Primary outcome(s)
Overall severity of dyspepsia symptoms measured using the 7-point global overall symptom scale (GOSS) at baseline (0 day), 15th, 30th, and 60th days after treatment, and follow-up at 1 month after the expiration of the intervention

Key secondary outcome(s))
Quality-of-life, adverse reactions and other indicators measured using the 36-Item Short Form Survey (SF-36) at baseline (0 day), 15th, 30th, and 60th days after treatment, and follow-up at 1 month after the expiration of the intervention

Completion date
08/04/2023

Eligibility

Key inclusion criteria
1. Aged 18 to 80 years old with no gender restrictions
2. Meet the diagnostic criteria for functional dyspepsia in Rome III (the absence of organic dyspepsia confirmed by endoscope)
3. Normal gastroscopy results in the past 1 year, and no other organic lesions in the gastrointestinal tract
4. No mental illness (Mini Mental State Questionnaire, MMSE ≥ 20)
5. Able to take food orally
6. Volunteered to accept intervention and signed the informed consent
7. Compliance with treatment completion and follow-up

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Upper age limit
80 years

Sex
All

Total final enrolment
64

Key exclusion criteria
1. Severe cognitive impairment
2. Abnormal electrocardiogram
3. Organic digestive tract disease
4. History of gastrointestinal surgery
5. Diabetes
6. Malignant tumors
7. Other diseases
8. Taking traditional Chinese medicine preparations
9. Pregnancy and breast-feeding or planning to become pregnant within 6 months
10. History of allergic reactions related to Chinese medicine or rice paste
11. Impairment of liver and kidney function:
11.1 Total bilirubin, alanine aminotransferase or aspartate aminotransferase> 2 times the upper limit of normal
11.2. Serum creatinine> 2 times the upper limit of normal
12. Drugs that affect digestive function taken within the past month and during the study period:

12.1. Gastrointestinal motility drugs
12.2. Anti-Helicobacter pylori drugs
12.3. Antidepressants
12.4. Antianxiety drugs
12.5. Acid-suppressing drugs (PPIs and H2 receptor blockers)
13. A place of residence that is too far, unwilling or unable to complete the return visit
14. H. pylori positive by Carbon-13 urea breath test at the time of screening.

Date of first enrolment
08/01/2022

Date of final enrolment
08/01/2023

Locations

Countries of recruitment
China

Study participating centre
Beijing Shijitan Hospital
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Sponsor information

Organisation
Beijing Shijitan Hospital

ROR
https://ror.org/0569k1630

Funder(s)

Funder type
Research organisation

Funder Name

Chinese Academy of Agricultural Sciences

Alternative Name(s)
, , CAAS

Funding Body Type
Government organisation

Funding Body Subtype
Universities (academic only)

Location
China

Results and Publications

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

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		07/01/2024	08/03/2024	Yes	No