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Treatment of Shugan Hewei recipe in the treatment of gastroesophageal reflux disease (GERD)

Submission date 24/03/2015	**Recruitment status** No longer recruiting	[_] Prospectively registered [_] Protocol [_] Statistical analysis plan [X] Results [_] Individual participant data
Registration date 08/04/2015	**Overall study status** Completed	
Last Edited 17/05/2023	**Condition category** Digestive System	

Plain English summary of protocol

Background and study aims
Gastro-oesophageal reflux disease (GORD) is a common condition where acid from the stomach leaks out of the stomach and up into the oesophagus (gullet). Some patients' symptoms persist despite treatment with drugs. This study aims to see whether Shugan Hewei recipe might help those with GERD. Previous studies have suggested a benefit but this needs confirmation.

Who can participate?
Patients diagnosed by their doctors as having gastroesophageal reflux disease (GERD).

What does the study involve?
Participants will be randomly allocated to take either Shugan Hewei recipe herbal granules and a placebo (dummy) tablet for 4 weeks, or an Omeprazole tablet and placebo granules for 4 weeks.

What are the possible benefits and risks of participating?
We are hoping that towards the end of the 4-week period reflux and heartburn will improve. The drugs have been used for many years and the side effects are well recognised. Only a very few will 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. Beijing Hospital of Traditional Chinese Medicine affiliated to Capital Medical University
2. Peking Union Medical College Hospital
3. Beijing Shijitan Hospital
4. Shengjing Hospital of China Medical University

When is the study starting and how long is it expected to run for?
From April 2015 to September 2017.

Who is funding the study?
Beijing Municipal Administration of Hospitals (China).

Who is the main contact?
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Contact information

Type(s)
Scientific

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Additional identifiers

Study information

Scientific Title
Efficacy of Shugan Hewei recipe in the treatment of gastroesophageal reflux disease (GERD): a multicentre parallel-group randomised controlled trial

Study objectives
The purpose of the trial is to define the clinical benefit of Shugan Hewei recipe in gastroesophageal reflux disease (GERD). The primary endpoint is to assess the effect of Shugan Hewei recipe on GERD questionnaire Score.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee of Beijing Hospital of Traditional Chinese Medicine affiliated to Capital Medical University, 03/07/2015, NO.2015BL-007-02

Study design
Multicentre parallel-group double-blind randomised controlled trial

Primary study design
Interventional

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Gastroesophageal reflux disease (GERD)

Interventions
Participants will be randomized to receive either:
1. Shugan Hewei recipe herbal granules and matching Omeprazole placebo tablet for 4 weeks or
2. Omeprazole tablet and matching Shugan Hewei recipe herbal placebo granules for 4 weeks.

Herbal granules were dissolved in 300 ml of boiled water, 150 ml twice daily.
Omeprazole tablet 20 mg once a day, on an empty stomach.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
Omeprazole, Shugan Hewei recipe herbal granules

Primary outcome(s)
GERD questionnaire score, measured at baseline, 2 weeks and 4 weeks

Key secondary outcome(s))
1. Traditional Chinese Medicine syndromes of IBS score, measured at baseline, 2 weeks and 4 weeks
2. High resolution manometry (HRM), measured at baseline and 4 weeks

Completion date
30/09/2017

Eligibility

Key inclusion criteria
1. Patients with GERD, GERD questionnaire score >8
2. Patients able to give informed consent
3. Female patients of childbearing potential who are willing to use at least one highly effective contraceptive method
4. Aged 18-65 years, either sex

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group

Adult

Lower age limit
18 years

Upper age limit
65 years

Sex
All

Total final enrolment
288

Key exclusion criteria
1. Women who are pregnant or breastfeeding
2. Patients with Zollinger-Ellison syndrome or primary esophageal dynamic disease
3. Patients with serious concomitant diseases e.g. cardiovascular, renal, hepatic, respiratory, neurological, endocrine, hematopoietic etc
4. Patients with early warning symptoms of malignant tumors
5. Patients who were taking proton-pump inhibitor or H2 receptor antagonist during the prior 2 weeks
6. Patients who have allergic constitution or known to be allergic to the drug used in this trial
7. Patients who are involved in other trials
8. Patients with poor compliance or other reasons that the researcher considered not to be appropriate to participate in this trial

Date of first enrolment
01/04/2015

Date of final enrolment
31/08/2017

Locations

Countries of recruitment
China

Study participating centre
Beijing Hospital of Traditional Chinese Medicine affiliated to Capital Medical University
Beijing
China
100010

Study participating centre
Peking Union Medical College Hospital
Beijing

China
100032

Study participating centre
Beijing Shijitan Hospital
Beijing
China
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Study participating centre
Shengjing Hospital of China Medical University
Shenyang
China
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Sponsor information

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

ROR
https://ror.org/057vq6e26

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Beijing Municipal Administration of Hospitals

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		28/07/2021	17/05/2023	Yes	No