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

Submission date	Recruitment status No longer recruiting	<ul><li>Prospectively registered</li></ul>		
24/03/2015		☐ Protocol		
Registration date	Overall study status	Statistical analysis plan		
08/04/2015	Completed	[X] Results		
Last Edited	Condition category	[] Individual participant data		
17/05/2023	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? Dr Shengsheng Zhang zhss2000@163.com

### Contact information

#### Type(s)

Scientific

#### Contact name

Dr Luqing Zhao

#### **ORCID ID**

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#### Additional identifiers

#### Protocol serial number

N/A

## 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

#### 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