

# Efficacy of banhasasim-tang on functional dyspepsia

<b>Submission date</b> 04/09/2009	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered
		<input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 18/09/2009	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan
		<input checked="" type="checkbox"/> Results
<b>Last Edited</b> 06/03/2019	<b>Condition category</b> Digestive System	<input type="checkbox"/> Individual participant data

**Plain English summary of protocol**  
Not provided at time of registration

## Contact information

**Type(s)**  
Scientific

**Contact name**  
Prof Jae-Woo Park

**Contact details**  
149, East-West Neo Medical Centre  
Kyung Hee University  
Sangil-dong, Gangdong-gu  
Seoul  
Korea, South  
134-727  
+82 (0)2 440 6219  
pjaw2907@khu.ac.kr

## Additional identifiers

**ClinicalTrials.gov (NCT)**  
NCT00987805

**Protocol serial number**  
B090029

## Study information

**Scientific Title**

Efficacy of banhasasim-tang on functional dyspepsia: a randomised, double blind, placebo controlled, two-centre trial

**Study objectives**

Banhasasim-tang could improve symptoms of dyspepsia in adult functional dyspepsia patients.

**Ethics approval required**

Old ethics approval format

**Ethics approval(s)**

1. Kyung Hee University Oriental Medical Centre approved on 30th April 2009
2. Oriental Medical Centre, East-West Neo Medical Centre, Kyung Hee University approved on 9th March 2009

**Study design**

Two-centre randomised double-blind two-arm placebo-controlled trial

**Primary study design**

Interventional

**Study type(s)**

Treatment

**Health condition(s) or problem(s) studied**

Functional dyspepsia

**Interventions**

1. Patients in banhasasim-tang group receive a pack of this herbal formula (3 g), that is formed in granules, for three times a day after meal
2. Patients in placebo group receive a pack of corn-starch granules (3 g) that have the same color and taste as banhasasim-tang granules for three times a day after meal

The total duration of both arms is 14 weeks. Timepoints are as follows:

Visit 1: Screening

Visit 2: Randomisation and first administration of banhasasim-tang or placebo for 2 weeks

Visit 3: Follow-up and second administration for 2 weeks

Visit 4: Follow-up and third administration for 2 weeks

Visit 5: Treatment finish and follow-up

Visit 6: 4 weeks later of treatment finish and follow-up

Visit 7: 8 weeks later of treatment finish and follow-up

**Intervention Type**

Drug

**Phase**

Not Applicable

**Drug/device/biological/vaccine name(s)**

Banhasasim-tang

## **Primary outcome(s)**

1. Gastrointestinal Symptom (GIS) score: This score comprises 10 dyspeptic symptoms (epigastric pain/upper abdominal pain, abdominal cramps, fullness, early satiety, loss of appetite, sickness, nausea, vomiting, retrosternal discomfort, and acidic regurgitation/heartburn)
2. Symptom severity is assessed by 5-point Likert Scale (0: none, 1: slight, 2: moderate, 3: severe, 4: very severe)

Assessment will be conducted at baseline, 2, 4, and 6 weeks after administration, 4 and 8 weeks after treatment finish.

## **Key secondary outcome(s)**

1. Visual Analogue Scale (VAS) for overall discomfort due to dyspepsia, assessed at baseline, 2, 4, and 6 weeks after administration, 4 and 8 weeks after treatment finish
2. Functional Dyspepsia-related Quality of Life (FD-QoL), assessed at baseline, 2, 4, and 6 weeks after administration, 4 and 8 weeks after treatment finish
3. Electrogastrography (EGG) will be conducted at baseline and 6 weeks after administration

## **Completion date**

31/01/2011

# **Eligibility**

## **Key inclusion criteria**

1. Typical functional dyspepsia according to ROME III criteria
  - 1.1. One or more of:
    - 1.1.1. Bothersome post-prandial fullness
    - 1.1.2. Early satiation
    - 1.1.3. Epigastric pain
    - 1.1.4. Epigastric burning
  - 1.2. No evidence of structural disease (including at upper endoscopy) that is likely to explain the symptoms
2. The presence of 'moderate' as the degree of severity for at least three Gastrointestinal Symptom (GIS) score symptoms
3. Before participation of trial, epigastric pain or discomfort has persisted in a permanent or recurrent form for a minimum period of 12 weeks
4. Regardless of sex, age range between 18 and 75 year old
5. Written and informed consent

## **Participant type(s)**

Patient

## **Healthy volunteers allowed**

No

## **Age group**

Adult

## **Lower age limit**

18 years

**Upper age limit**

75 years

**Sex**

All

**Key exclusion criteria**

1. History of peptic ulcer or gastroesophageal reflux disease (GERD)
2. Current prominent symptoms of irritable bowel syndrome or GERD
3. Presence of the following alarm symptoms:
  - 3.1. Severe weight loss
  - 3.2. Black or tar stool
  - 3.3. Dysphagia
4. Presence of the following diseases (like cholangitis, pancreatitis, etc.) or uncontrolled severe organ disorders
5. Women in pregnancy and lactation
6. History of gastrointestinal surgery or taking any drugs that may significantly alter digestive system
7. Participation of other clinical trials within the last 3 months
8. Severe mental problems or drug abuse
9. Judged by expert that they are appropriate to participate in this study

**Date of first enrolment**

15/09/2009

**Date of final enrolment**

31/01/2011

**Locations****Countries of recruitment**

Korea, South

**Study participating centre**

149, East-West Neo Medical Centre

Seoul

Korea, South

134-727

**Sponsor information****Organisation**

Korea Health Industry Development Institute (KHIDI) (South Korea)

ROR

https://ror.org/00fdzyk40

## Funder(s)

### Funder type

Government

### Funder Name

Korea Health Industry Development Institute (KHIDI) (South Korea) - The 2009 grant of the Traditional Korean Medicine R&D Project, Ministry for Health & Welfare & Family Affairs

## Results and Publications

### Individual participant data (IPD) sharing plan

### IPD sharing plan summary

Not provided at time of registration

### Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Results article</a>	results	01/07/2013	06/03/2019	Yes	No
<a href="#">Protocol article</a>	protocol	30/07/2010		Yes	No