

Efficacy of banhasasim-tang on functional dyspepsia

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

Primary study design

Interventional

Study design

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

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?
Results article	results	01/07/2013	06/03/2019	Yes	No
Protocol article	protocol	30/07/2010		Yes	No