ISRCTN51910678 https://doi.org/10.1186/ISRCTN51910678

Efficacy of banhasasim-tang on functional dyspepsia

Submission date	Recruitment status	[_] Prospectively registered
04/09/2009	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/09/2009	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
06/03/2019	Digestive System	

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
pjw2907@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 disese (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