ISRCTN66631530 https://doi.org/10.1186/ISRCTN66631530

Treatment of Jianpi Shugan recipe in the treatment of diarrhoea-predominant irritable bowel syndrome (IBS-D)

Submission date 19/03/2015	**Recruitment status** No longer recruiting	[X] Prospectively registered [_] Protocol
Registration date 08/04/2015	**Overall study status** Completed	[_] Statistical analysis plan [_] Results
Last Edited 08/04/2015	**Condition category** Digestive System	[_] Individual participant data [_] Record updated in last year

Plain English summary of protocol

Background and study aims.
Diarrhoea-predominant irritable bowel syndrome (IBS-D) affects around 3% of the population and is characterised by abdominal pain and frequent loose bowel movements. There are few treatments for these symptoms that work and this study aims to see whether Jianpi Shugan recipe might help those with IBS-D. Previous studies have suggested a benefit but this needs to be confirmed.

Who can participate?
Patients diagnosed by their doctors as having diarrhoea-predominant irritable bowel syndrome .

What does the study involve?
Patients will be randomly allocated either to take Jianpi Shugan recipe herbal granules with a placebo (dummy) tablet, or to take Pinaverium with placebo granules for 4 weeks. At the beginning of the study, an examination of the lower bowel will be made and a small specimen taken from the lining (biopsy). This procedure is routinely performed to identify the different causes of diarrhoea.

What are the possible benefits and risks of participating?
We are hoping that towards the end of the 4-week period diarrhoea and abdominal pain will improve. The drugs has been used for many years and the side effects are well recognised. Only a very few will not tolerate the drug because of abdominal discomfort, constipation, diarrhoea, nausea, rash etc.

Where is the study run from?
Beijing Hospital of Traditional Chinese Medicine affiliated to Capital Medical University
Beijing Chaoyang Hospital affiliated to Capital Medical University
The First Affiliated Hospital of Henan University of TCM
First Teaching Hospital of Tianjin University of TCM
Second Affiliated Hospital of Tianjin University of TCM

When is the study starting and how long is it expected to run for?
From April 2015 and to March 2016.

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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100010

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
N/A

Study information

Scientific Title
Efficacy of Jianpi Shugan recipe in the treatment of diarrhoea-predominant irritable bowel syndrome (IBS-D): a multicentre parallel-group randomised controlled trial

Study objectives
The purpose of the trial is to define the clinical benefit of Jianpi Shugan recipe in diarrhoea-predominant irritable bowel syndrome (IBS-D) . The primary endpoint is to assess the effect of Jianpi Shugan recipe on IBS Symptom Severity Score (IBS-SSS).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee of Beijing Hospital of Traditional Chinese Medicine affiliated to Capital Medical University, 15/02/2015, NO.2015BL-008-02

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

Primary study design
Interventional

Secondary study design
Randomised parallel trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet

Health condition(s) or problem(s) studied
Diarrhoea-predominant irritable bowel syndrome (IBS-D)

Interventions
Patients will be randomized to receive either Jianpi Shugan recipe herbal granules + matching Pinaverium placebo or Pinaverium + matching Jianpi Shugan recipe herbal placebo granules for 4 weeks. Herbal granules were dissolved in 300 ml of boiled water, 150 ml twice daily, Pinaverium 50 mg three times a day.

Intervention Type
Drug

Phase
Not Applicable

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

Primary outcome measure
IBS Symptom Severity Score (IBS-SSS) measured at baseline, 2 weeks and 4 weeks

Secondary outcome measures
1. Traditional Chinese Medicine syndromes of IBS score measured at baseline, 2 weeks and 4 weeks

2. Defection state questionnaire (DSQ) for IBS noted by patients daily
3. Irritable bowel syndrome-quality of life questionnaire (IBS-QOL) at baseline and 4 weeks
4. Serum concentration of serotonin at baseline and 4 weeks

Overall study start date
01/04/2015

Completion date
31/03/2016

Eligibility

Key inclusion criteria
1. Patients with IBS-D meeting the Rome III criteria
2. Patients meeting the Traditional Chinese Medicine syndrome of liver-depression and spleen-deficiency criteria
3. Patients able to give informed consent
4. Female patients of childbearing potential are willing to use at least one highly effective contraceptive method
5. Aged 18-65 years, either sex

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Upper age limit
65 Years

Sex
Both

Target number of participants
260

Key exclusion criteria
1. Women who are pregnant or breastfeeding
2. Prior abdominal surgery which may cause bowel symptoms similar to IBS
3. Patients with the following diarrhea conditions: infection, systemic diseases, poisoning or cancer
4. Patients with serious concomitant diseases e.g. cardiovascular, renal, hepatic, respiratory, neurological, endocrine, hematopoietic etc
5. Patients with a history of alcoholic or drug abuse
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
01/06/2015

Date of final enrolment
01/03/2016

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
Beijing Chaoyang Hospital affiliated to Capital Medical University
Beijing
China

Study participating centre
The First Affiliated Hospital of Henan University of TCM
Zhengzhou
China

Study participating centre
First Teaching Hospital of Tianjin University of TCM
Tianjin
China

Study participating centre
Second Affiliated Hospital of Tianjin University of TCM
Tianjin
China

Sponsor information

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

Sponsor details
No. 23 Meishuguan Back Street
Dongcheng District
Beijing
China
100010

Sponsor type
Hospital/treatment centre

ROR
https://ror.org/057vq6e26

Funder(s)

Funder type
Hospital/treatment centre

Funder Name
Beijing municipal administration of hospitals

Results and Publications

Publication and dissemination plan
To be confirmed at a later date

Intention to publish date

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Available on request