

Effects of the Renzhuchangle granule on diarrhoea-predominant irritable bowel syndrome

Submission date 21/11/2018	Recruitment status No longer recruiting	☒ Prospectively registered ☐ Protocol
Registration date 30/11/2018	Overall study status Completed	☐ Statistical analysis plan ☐ Results
Last Edited 30/01/2023	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 symptoms include abdominal pain and frequent loose bowel movements. This study aims to determine whether the Renzhuchangle granule might help those IBS-D, as previous studies have shown it may be beneficial

Who can participate?

Adults aged 18-65 who have been diagnosed by their doctors as having diarrhoea-predominant irritable bowel syndrome

What does the study involve?

Participants will be randomly allocated to one of three treatments:

1. Renzhuchangle granule treatment - 8 g, 3 times per day for 8 weeks
2. Placebo treatment - 8 g, 3 times per day for 8 weeks
3. Renzhuchangle granule treatment - 4 g, 3 times per day for 8 weeks AND placebo treatment - 4 g, 3 times per day for 8 weeks

There will be an 8 week follow up period following 8 weeks of medication.

What are the possible benefits and risks of participating?

The possible benefit of participating is that the Renzhuchangle granule may improve symptoms of diarrhoea and abdominal pain, although this cannot be guaranteed. The possible risks of participating is that the treatment may cause side effects including abdominal discomfort, constipation, diarrhoea, nausea and rash, although this is unlikely.

Where is the study run from?

Beijing Hospital of Traditional Chinese Medicine, Capital Medical University and 4 other hospitals in China

When is the study starting and how long is it expected to run for?

December 2018 to December 2020

Who is funding the study?
Purapharm (Nanning) Pharmaceuticals Co. Limited (China)

Who is the main contact?
Dr Shengsheng Zhang
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Contact information

Type(s)
Public

Contact name
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Additional identifiers

Protocol serial number
2018-09-26

Study information

Scientific Title
Effects of Renzhuchangle grannule on diarrhoea-predominant irritable bowel syndrome: a
randomised, double-blind, placebo-controlled phase IIa study

Study objectives
The Renzhuchangle granule is more effective in the treatment of diarrhoea-predominant
irritable bowel syndrome than the placebo

Ethics approval required
Old ethics approval format

Ethics approval(s)
Ethics committee of Beijing Hospital of Traditional Chinese Medicine affiliated to Capital
Medical University, 05/11/2018, NO.2017BL-058-04

Primary study design
Interventional

Study design
Interventional multi-centre double-blind randomised placebo-controlled trial

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Diarrhoea-predominant irritable bowel syndrome (IBS-D)

Interventions

Participants are randomly allocated to one of three groups using SAS9.10 software:

1. Renzhuchangle granule 8 g, taken orally three times per day for 8 weeks
 2. Renzhuchangle granule 4 g taken orally three times per day for 8 weeks, and matching Renzhuchangle granule placebo 4 g taken orally three times per day for 8 weeks
 3. Matching Renzhuchangle granule placebo 8 g, taken orally three times per day for 8 weeks
- Following completion of this 8 week period, there is another 8 week follow-up period.

Patients and investigators are all blinded to treatment allocation.

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

Renzhuchangle granule

Primary outcome(s)

The following will be assessed by reviewing patient notes at the baseline and weekly from weeks 1-8:

1. Abdominal pain score
2. Stool consistency

Key secondary outcome(s)

1. Abdominal bloating, assessed by reviewing patient notes at the baseline and after 2, 4 and 8 weeks
2. IBS symptom severity, assessed using the Irritable Bowel Syndrome Symptom Severity Scoring System (IBS-SSS) at the baseline and after 8 weeks
3. Traditional Chinese Medicine syndromes of IBS score, assessed at the baseline and after 8 weeks
4. Quality of life, assessed using the Irritable Bowel Syndrome Quality of Life questionnaire (IBS-QOL) at the baseline and after 8 weeks

Completion date

31/12/2020

Eligibility

Key inclusion criteria

1. Diarrhoea-predominant irritable bowel syndrome (IBS-D) meeting the Rome IV criteria
2. Meeting the Traditional Chinese Medicine syndrome of liver-depression and spleen-deficiency criteria
3. Aged 18 to 65

4. Voluntary acceptance of the medication
5. Signed informed consent
6. Average daily worst abdominal pain score ≥ 3 during the last week of screening phase
7. More than two days of ≥ 1 loose stools (Bristol Stool Scale 6 or 7) during the last week of screening phase

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 Years

Sex

All

Key exclusion criteria

1. Prior abdominal surgery which may cause bowel symptoms similar to IBS
2. Diarrhoea as a result of any of the following:
 - 2.1. Infection
 - 2.2. Systemic diseases
 - 2.3. Poisoning
 - 2.4. Cancer
3. Serious concomitant diseases, including cardiovascular, renal, hepatic, respiratory, neurological, endocrine or haematopoietic diseases
4. History of alcohol or drug abuse
5. Allergic constitution or known to be allergic to the drug used in this trial
6. Involved in other trials
7. Pregnant or breastfeeding, or plan to become pregnant soon
8. Poor compliance or any other reason the research believes they may not be appropriate to participate in this trial

Date of first enrolment

01/12/2018

Date of final enrolment

31/12/2019

Locations**Countries of recruitment**

China

Study participating centre

Beijing Hospital of Traditional Chinese Medicine, Capital Medical University
Beijing
China
10010

Study participating centre
First Teaching Hospital of Tianjin University of Traditional Chinese Medicine
Tianjin
China
300193

Study participating centre
Ruikang Hospital Affiliated to Guangxi University of Chinese Medicine
Nanning
China
530011

Study participating centre
West China HospitalSichuan University
Chengdu
China
610044

Study participating centre
Hubei Province Hospital of Traditional Chinese Medicine
Wuhan
China
430061

Sponsor information

Organisation
Purapharm (Nanning) Pharmaceuticals Co. Limited

Funder(s)

Funder type

Industry

Funder Name

Purapharm (Nanning) Pharmaceuticals Co. Limited

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are not expected to be made available due to data security.

IPD sharing plan summary

Not expected to be made available