ISRCTN42639030 https://doi.org/10.1186/ISRCTN42639030

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

Submission date 21/11/2018	**Recruitment status** No longer recruiting	[X] 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
zhss2000@163.com

Contact information

Type(s)
Public

Contact name
Prof Shengsheng Zhang

Contact details
Beijing Hospital of Traditional Chinese Medicine Affiliated to Capital Medical University, 23 Meishuguanhou Street, Dongcheng District
Beijing
China
100010

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

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

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
No participant information sheet available

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 measure
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

Secondary outcome measures
1. Abdominal bloating, assessed by reviewing patient notes at the baseline and after 2, 4 and 8 weeks
2. IBS symptom servirty, 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

Overall study start date
01/03/2018

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

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
108

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 believers 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

Sponsor details
NO.46 keyuan streetXixiangtang District
Nanning
China
530000

Sponsor type
Industry

Funder(s)

Funder type
Industry

Funder Name
Purapharm (Nanning) Pharmaceuticals Co. Limited

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
31/12/2021

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