

Effectiveness and safety of Compound Glutamine Entersoluble Capsules versus placebo for diarrhea-predominant irritable bowel syndrome

Submission date 07/01/2020	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 09/01/2020	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 05/01/2022	Condition category Digestive System	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Irritable Bowel Syndrome (IBS) is a functional bowel disease characterized by recurrent abdominal pain associated with bowel movements or changes in bowel habits. It has been estimated that IBS affects approximately 11% of the global population. IBS can be categorized into four subtypes, diarrhea-predominant irritable bowel syndrome (IBS-D) is one of them and account for about 40% of all IBS patients. IBS-D significantly reduces the quality of life of patients and affects the patient's daily activities. The specific pathogenesis of IBS has not been clarified clinically, and no specific therapeutic drugs have been found.

Compound Glutamine Entersoluble Capsules (CGEC) is an integrated Chinese and western medicine compound preparation made of Sijunzi Decoction (Ren shen, Bai Zhu, Fu Ling, Gan Cao) and L-Glutamine. It was approved by the Chinese FDA, and has been used in clinical practice for more than 20 years for the treatment of acute or chronic intestinal diseases. Modern pharmacological studies proved that CGEC could improve intestinal absorption and movement, promote the secretion of gastrointestinal hormones, and enhance intestinal immunity. It can also repair damaged intestinal mucosa and strengthen the defence function of the mucosal barrier. The aim of this study is to evaluate the clinical effectiveness and safety of Compound Glutamine Entersoluble Capsules in the treatment of diarrhea-predominant irritable bowel syndrome.

Who can participate?

Patients aged 18 to 70 years old with diarrhea-predominant irritable bowel syndrome

What does the study involve?

Participants are randomly allocated into two groups. One group receives Compound Glutamine Entersoluble Capsules for 4 weeks, and the control group receives a placebo (dummy drug) of Compound Glutamine Entersoluble Capsules for 4 weeks.

What are the possible benefits and risks of participating?

If successful, the medicine has the potential to preserve and enhance the benefits of rehabilitation for patients with diarrhea-predominant irritable bowel syndrome. This may reduce hospital admissions and improve quality of life. The tested drug may have some minor adverse effect during the treatment.

Where is the study run from?

1. Wangjing Hospital, China Academy of Chinese Medical Sciences, Beijing, China
2. Shanxi Provincial Hospital of Traditional Chinese Medicine, Taiyuan, Shanxi, China
3. Nankai Hospital of Tainjin, Tianjin, China

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

January 2020 to May 2022 (updated 08/01/2021, previously: June 2021)

Who is funding the study?

Di Ao Chengdu Pharmaceutical Co., Ltd (China)

Who is the main contact?

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

Nil known

Study information

Scientific Title

Compound Glutamine Entersoluble Capsules for diarrhea-predominant irritable bowel syndrome: a randomized, double-blind, placebo-controlled, multi-center clinical trial

Study objectives

Compared with placebo, Compound Glutamine Entersoluble Capsules may be effective and safe for diarrhea-predominant irritable bowel syndrome.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 31/12/2019, Medical Ethics Committee of Wangjing Hospital of CACMS (Hua-Jia-Di Street, Chaoyang District, Beijing; Tel: +86 (0)10-84739681; Email: wjyyec@126.com); ref: WJEC-KT-2019-009-P002

Study design

Randomized double-blind placebo-controlled multi-center clinical trial

Primary study design

Interventional

Secondary study design

Randomised parallel trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

No participant information sheet available

Health condition(s) or problem(s) studied

Diarrhea-predominant irritable bowel syndrome

Interventions

In this study, the researchers will allocate randomly participants into two groups using SAS software to generate a sequence of random numbers. One group receives Compound Glutamine Entersoluble Capsules for 4 weeks, and the control group receives placebo of Compound Glutamine Entersoluble Capsules for 4 weeks.

The dosage given: 3 capsules/time

The frequency of treatment: 3 times/day

The total duration of follow-up: 8 weeks \pm 3 days

Intervention Type

Drug

Phase

Phase II

Drug/device/biological/vaccine name(s)

Compound Glutamine Entersoluble Capsules

Primary outcome measure

1. The degree of IBS symptom severity, measured using the scale of irritable bowel syndromes symptom severity score (IBS-SSS) at baseline, 2 weeks \pm 3 days (duration of treatment), 4 weeks \pm 3 days (end of treatment), 8 weeks \pm 3 days (end of follow-up)
2. Stool frequency: the average daily number of voluntary defecations in the week before each timepoint at baseline, 2 weeks \pm 3 days (duration of treatment), 4 weeks \pm 3 days (end of treatment), 8 weeks \pm 3 days (end of follow-up)
3. Stool consistency measured using the Bristol stool scale at baseline, 2 weeks \pm 3 days (duration of treatment), 4 weeks \pm 3 days (end of treatment), 8 weeks \pm 3 days (end of follow-up)

Secondary outcome measures

1. Quality of life measured using the scale of IBS-quality of life (IBS-QOL) at baseline, 4 weeks \pm 3 days (end of treatment)
2. Anxiety of patient measured using the self-rating anxiety scale (SAS) at baseline, 4 weeks \pm 3 days (end of treatment)
3. Depression of patient measured using the self-rating depression scale (SDS) at baseline, 4 weeks \pm 3 days (end of treatment)
4. Safety assessed by:
 - 4.1. Routine examination (blood routine, urine routine, stool routine + OB) at baseline, 4 weeks \pm 3 days (end of treatment)
 - 4.2. Biochemical indexes including liver function (ALT, AST), kidney function (BUN, Cr) measured at baseline, 4 weeks \pm 3 days (end of treatment)
 - 4.3. Electrocardiogram measured at baseline, 4 weeks \pm 3 days (end of treatment)
 - 4.4. Adverse reactions, such as rash, constipation, or other special symptoms, recorded at any time during the treatment by the patient: Incidence of adverse reactions = (number of adverse reactions / total cases) \times 100%

4.5. Adverse events, such as loss of function or disability, life-threatening or even death, recorded at any time during the treatment by the researchers: incidence of adverse events = (number of adverse events / total cases) × 100%

Overall study start date

01/01/2020

Completion date

31/05/2022

Eligibility

Key inclusion criteria

1. Aged 18 to 70 years, male or female
2. Those who meet IBS-D Rome IV diagnostic criteria
3. Those who meet any one type syndrome of the diagnostic criteria for TCM syndromes, including: Liver Depression and Spleen Deficiency Syndrome, Spleen Deficiency and Wetness Sheng Syndrome, Spleen and Kidney Yang Deficiency Syndrome, Spleen and Stomach Damp-Heat Syndrome, Cold and Heat Miscellaneous Syndrome
4. IBS-SSS score ≥ 75
5. The patient did not take any drugs related to the treatment of the disease at least one week before entering the study, and did not participate in other ongoing studies
6. Patients who had a colonoscopy at a 3A (Tertiary) hospital within one year and had an examination report
7. Accept the trial voluntarily and sign the informed consent form. The informed consent process complies with Good Clinical Practice (GCP)
8. Long term residence in the place where the treatment is given

Participant type(s)

Patient

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

198

Total final enrolment

198

Key exclusion criteria

1. Irritable bowel syndrome with predominant irregular bowel habits
2. Patients with tumors or organic lesions in the heart, liver, kidney, etc
3. Patients with mental illness

4. Patients with tumors or organic lesions in gastrointestinal tract, such as pancreatitis, intestinal polyps (excluding those with polypectomy for more than half a month), intestinal diverticulum, history of colon or rectal cancer, history of inflammatory bowel disease, intestinal tuberculosis, etc
5. Patients with metabolic diseases that affect the dynamics of the digestive tract, such as thyroid disease, diabetes, etc
6. Those who with allergic constitution or allergic to the composition of the studied drug
7. Patients with a history of abdominal or pelvic surgery, such as cholecystectomy
8. According to the investigator's judgment, the patient has a situation that reduces the likelihood of enrollment or complicates enrollment, such as frequent changes in the work environment and other situations that are prone to loss of follow-up

Date of first enrolment

15/01/2020

Date of final enrolment

31/12/2021

Locations

Countries of recruitment

China

Study participating centre

Wangjing Hospital, China Academy of Chinese Medical Sciences

Hua-Jia-Di Street, Chaoyang District

Beijing

China

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Study participating centre

Shanxi Provincial Hospital of Traditional Chinese Medicine

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Taiyuan

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Study participating centre

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Funder(s)

Funder type

Industry

Funder Name

Di Ao Chengdu Pharmaceutical Co., Ltd., China

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal, approximately December 2021.

Intention to publish date

31/12/2022

Individual participant data (IPD) sharing plan

Current individual participant data (IPD) sharing statement as of 05/01/2022:

With regard to IPD, the datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication.

Previous individual participant data (IPD) sharing statement:

The data sharing plans for the current study are limited upon the contract with the company and might be made available upon agreement from the company.

IPD sharing plan summary

Published as a supplement to the results publication