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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

Registration date
09/01/2020

Overall study status
Completed

Last Edited
05/01/2022

Condition category
Digestive System

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] 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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Scientific

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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 ± 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 ± 3 days (duration of treatment), 4 weeks ± 3 days (end of treatment), 8 weeks ± 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 ± 3 days (duration of treatment), 4 weeks ± 3 days (end of treatment), 8 weeks ± 3 days (end of follow-up)
3. Stool consistency measured using the Bristol stool scale at baseline, 2 weeks ± 3 days (duration of treatment), 4 weeks ± 3 days (end of treatment), 8 weeks ± 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 ± 3 days (end of treatment)
2. Anxiety of patient measured using the self-rating anxiety scale (SAS) at baseline, 4 weeks ± 3 days (end of treatment)
3. Depression of patient measured using the self-rating depression scale (SDS) at baseline, 4 weeks ± 3 days (end of treatment)
4. Safety assessed by:
4.1. Routine examination (blood routine, urine routine, stool routine + OB) at baseline, 4 weeks ± 3 days (end of treatment)
4.2. Biochemical indexes including liver function (ALT, AST), kidney function (BUN, Cr) measured at baseline, 4 weeks ± 3 days (end of treatment)
4.3. Electrocardiogram measured at baseline, 4 weeks ± 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) × 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
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Study participating centre
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Study participating centre
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Sponsor type
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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