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Chinese herbal medicine Shufeng Jiedu capsule for patients with mild to moderate COVID-19

Submission date	Recruitment status	[X] Prospectively registered
29/04/2022	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
03/05/2022	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
25/06/2024	Infections and Infestations	

Plain English summary of protocol

Background and study aims
Shufeng Jiedu capsule has the effect of dissipating wind, clearing heat, detoxifying and benefiting the pharynx (based on traditional Chinese medicine theory), so it can relieve the symptoms of COVID-19 patients and reduce their hospital stay. Thus, this study aims to find whether the Shufeng Jiedu capsule can help patients with mild coronavirus disease 2019 to relieve the symptoms and reduce their hospital stay.

Who can participate?
COVID-19 patients who are willing to take traditional Chinese medicine will be treated at designated isolation hospitals.

What does the study involve?
Participants will be randomly allocated to one of two groups a Shufeng Jiedu capsule or placebo for 5 days. After 5 days, they were followed up for 14 days after discharge.
Participants will be asked to give blood samples at the beginning of the study, on the 3rd day and on the 6th day to ensure basic safety. Participants will get 5-days of treatment and will complete the online questionnaires and assessments every day to ensure the effectiveness of symptoms.

What are the possible benefits and risks of participating?
Participants will get 5-day treatment for COVID-19. Medicines are provided free of charge.
Diarrhea, loose stools and yellow urine may occur after taking the medicine.

Where is the study run from?
The third people's hospital of Shenzhen, China.
The people's hospital of Bozhou, China.

When is the study starting and how long is it expected to run for?
April 2022 to September 2022

Who is funding the study?
Science and Technology Department of Anhui Province (China) and Anhui Jiren Pharmaceutical Co. LTD.

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
Chinese herbal medicine Shufeng Jiedu capsule for patients with mild to moderate coronavirus disease 2019 (COVID-19): A randomized double-blind placebo-controlled clinical trial

Study objectives
Shufeng Jiedu capsule has the effect of dissipating wind, clearing heat, detoxifying and benefiting the pharynx (based on traditional Chinese medicine theory), so it can relieve the symptoms of COVID-19 patients and reduce their time during their hospital stay.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 29/04/2022, Ethics Committee of the third people's hospital of Shenzhen (29 Bujibulan Road, Longgang District, Shenzhen, China; +86 0755-61222333-6539; szdsrmyyec@163.com), ref:[2022-097]

Study design
Multicenter randomized double-blind placebo-controlled clinical trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied
COVID-19 (SARS-CoV-2 infection)

Interventions
Experimental group: Shufeng Jiedu Capsule, taken orally for 5 days.
Control group: Shufeng Jiedu placebo, taken orally for 5 days.
After 5 days of treatment, all participants are no longer taking any Traditional Chinese medicine.
Participants were followed up for 14 days after discharge.
Participants are randomly allocated to groups using the coded boxes of pills.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)

Shufeng Jiedu Capsule

Primary outcome measure
Time to alleviation of symptoms (TTAS). Clinical symptoms are based on flu-like associated symptoms, including cough, stuffy nose, sore throat, fever or chills, muscle/joint pain, headache, and fatigue measured using self-report on a 0-3 scale (0 as no symptoms, 1 as mild symptoms, 2 as moderate symptoms and 3 as severe symptoms) at baseline, every day during the intervention (from 1st-6th day), and every day during follow-up (since discharged from hospital until 14th day).

Secondary outcome measures
1. Relief time and relief rate of other symptoms (other symptoms are determined according to the epidemic symptoms of COVID-19, including fever, respiratory symptoms (shortness of breath, dry throat, runny nose, etc.), and systemic symptoms (diarrhea, loss of appetite, body pain, smell, taste, nausea) measured scores from 0-3 (0 as no symptoms, 1 as mild symptoms, 2 as moderate symptoms and 3 as severe symptoms) at baseline, every day during the intervention (from 1st-6th day), and every day during follow-up (since discharged from hospital until 14th day).
2. The relief time of a single symptom contained in TTAS and the number of patients with symptom relief at each measurement point measured using patients' self-reported score at baseline, 6th day, the discharged day, 7th day and 14th day after discharge.
3. The number of negative nucleic acid transfers by RT-PCR (Ct values of N gene and ORF gene in two consecutive Novel Coronavirus nucleic acid tests ≥35), and the samples were nasal swabs at baseline, 3rd day, 6th day, the discharged day, 7th day and 14th day after discharge.
4. Laboratory tests required for leukocyte, lymphocyte, CRP, serum procalcitonin (PCT), inflammatory factor detection (interleukin-6), CD4/CD8, blood oxygen saturation and other signs monitoring at baseline, 3rd day, and 6th day.
5. Chest CT used to observe the changes in lung inflammation at baseline and on the discharge day.
6. Turn heavy rate measured using the number of patients at the 6th day.
7. Safety index (blood routine, coagulation function, electrolytes, urine routine, biochemical indicators) measured using laboratory tests at baseline, and 6th day. Adverse events were measured using patients' self-report during the intervention (from 1st-6th day), and every day during follow-up (since discharged from hospital until the 14th day).

Overall study start date
29/04/2022

Completion date
30/09/2022

Eligibility

Key inclusion criteria
1. Meet the mild and common diagnostic criteria for COVID-19;
2. The time interval between symptom onset and random enrollment was less than 3 days;
3. Adults (≥18 and ≤75 years);
4. Agree to participate in this study and accept random grouping;
5. Those who have signed informed consent and are not currently participating in other clinical trials of traditional Chinese medicine for COVID-19

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
200 in each group

Total final enrolment
407

Key exclusion criteria
1 Female patients in pregnancy and lactation;
2 Patients with a history of allergy to the test drug ingredients;
3. As judged by the investigator, or patients with acute episodes, cognitive insufficiency, or severe diarrhea (resulting in electrolyte disturbances and dehydration);
4. Continuous use of traditional Chinese medicine (tripartite and three-drug treatment) for COVID-19 within 3 days before enrollment;
5. Patients who are also participating in other clinical trials.

Date of first enrolment
03/05/2022

Date of final enrolment
15/09/2022

Locations

Countries of recruitment
China

Study participating centre
The third people's hospital of Shenzhen
29 Bujibulan Road, Longgang District, Shenzhen, China
Shenzhen
China
518112

Study participating centre

The people's hospital of Bozhou
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Sponsor type
Industry

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Funder(s)

Funder type
Government

Funder Name
Science and Technology Department of Anhui Province

Funder Name
Anhui Jiren Pharmaceutical Co. LTD

Results and Publications

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

Intention to publish date
31/12/2022

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available now due to the ethical requirement

IPD sharing plan summary
Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		27/05/2024	25/06/2024	Yes	No