

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

<b>Submission date</b> 29/04/2022	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 03/05/2022	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 25/06/2024	<b>Condition category</b> Infections and Infestations	<input type="checkbox"/> Individual participant data

## 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?

1. PhD. Chun-li Lu

Jennylyu@bucm.edu.cn

2. PhD. Xue-han Liu

xuehan\_liu@foxmail.com

3. Prof. Jian-ping Liu

Liujp@bucm.edu.cn

## Contact information

### Type(s)

Principal investigator

### Contact name

Prof Jian-ping Liu

### ORCID ID

<https://orcid.org/0000-0002-0320-061X>

### Contact details

11 Beisanhuan Dong Lu

Chaoyang District

Beijing

China

100029

+86 10-64286760

Liujp@bucm.edu.cn

## Additional identifiers

## 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

## **Study type(s)**

Treatment

## **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(s)**

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).

## **Key secondary outcome(s)**

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  $\geq 35$ ), 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).

**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 ( $\geq 18$  and  $\leq 75$  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

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**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**

No. 616, Duzhong Road, Bozhou Economic Development Zone, Bozhou, China  
Bozhou

China

236814

## Sponsor information

**Organisation**

Department of Science and Technology of Anhui Province

**ROR**

<https://ror.org/01e70gy59>

**Organisation**

Anhui Jiren Pharmaceutical Co. LTD

# Funder(s)

## Funder type

Government

## Funder Name

Science and Technology Department of Anhui Province

## Funder Name

Anhui Jiren Pharmaceutical Co. LTD

# 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 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?
<a href="#">Results article</a>		27/05/2024	25/06/2024	Yes	No