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Treatment of chronic fatigue syndrome by a Chinese herbal formula Sijunzi decoction

Submission date
23/05/2019

Recruitment status
No longer recruiting

Registration date
28/05/2019

Overall study status
Completed

Last Edited
22/04/2024

Condition category
Nervous System Diseases

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

Plain English summary of protocol

Background and study aims
Chronic fatigue syndrome (CFS), also known as idiopathic chronic fatigue (ICF), is characterized by chronic disabling fatigue in the absence of an alternative diagnosis. Recent studies reported that the prevalence in UK and US fluctuates from 0.2% to 2.6%. Although not life-threatening, CFS severely impacts quality of life. Currently, there is no drug treatment approved for CFS. Therefore, complementary and alternative medicine has been considered for clinicians and patients, among which Chinese Herbal Medicine (CHM) is one of the main therapies. In Traditional Chinese Medicine (TCM), spleen deficiency is most related to lack of energy, and Sijunzi Decoction is the fundamental prescription for spleen deficiency pattern. The aim of this study is to evaluate the efficacy and safety of Sijunzi Decoction for the treatment of CFS.

Who can participate?
CFS patients aged 18-80 who meet the diagnostic criteria developed by American CDC

What does the study involve?
Participants are randomly allocated to either the Sijunzi group or the placebo group, receiving either Sijunzi Decoction or placebo (dummy treatment) twice a day for two consecutive months. The severity of fatigue symptoms is measured using a questionnaire at the start of the study, 1 month, 2 months (treatment endpoint) and 3 months (follow-up endpoint). Blood and fecal samples are also collected at the start and the end of treatment to further explore the potential mechanism.

What are the possible benefits and risks of participating?
The potential benefit is that CFS patients with spleen deficiency pattern may have improved symptoms and quality of life from Sijunzi Decoction treatment. Sijunzi Decoction has been widely used in China from ancient times. No obvious side effects were documented. Considering that Ginseng Radix et Rhizoma (renshen) is a principal ingredient, possible side effects may include high blood pressure, insomnia and hyperactivity.

Where is the study run from?
Longhua Hospital Affiliated to Shanghai University of Traditional Chinese Medicine (China)

When is the study starting and how long is it expected to run for?
January 2019 to August 2021

Who is funding the study?
Shanghai Three-year Action Plan for Accelerating the Development of Traditional Chinese Medicine

Who is the main contact?
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Additional identifiers

Protocol serial number
PZYH-DL-1.1

Study information

Scientific Title
Sijunzi decoction for chronic fatigue syndrome with spleen deficiency pattern: a randomized controlled trial

Study objectives
To evaluate the efficacy and safety of Sijunzi decoction for chronic fatigue syndrome with spleen deficiency pattern by comparing with placebo.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 25/04/2019, Ethics Committee of Longhua Hospital Affiliated Shanghai University of Traditional Chinese Medicine (3rd Floor, Building 2, 725 South Wanping Road, Xuhui District, Shanghai 200032, China; Tel: +86 (0)21 64385700 1318; Email: lhtcmirb@sina.cn), approval No. 2019LCSY020

Primary study design
Interventional

Study design
Multi-centre double-blinded randomized placebo-controlled parallel clinical trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Chronic fatigue syndrome with spleen deficiency pattern

Interventions
Participants will be allocated to experimental or placebo arm based on the random number generated by SPSS 22.0 for Windows. Participants will be required to take the medicine twice daily for two consecutive months.

The experimental intervention is Sijunzi Decoction granules composed of four TCM herbs. One daily dosage contains 9 g Ginseng Radix et Rhizoma (Renshen), 9 g Atractylodis Macrocephalae Rhizoma (Baizhu), 9 g Poria (Fulin) and 6 g Glycyrrhizae Radix et Rhizoma Praeparata Cum Melle. The control intervention is placebo, which is comparable with Sijunzi Decoction granules in color, smell and taste.

Intervention Type
Other

Primary outcome(s)
Severity of fatigue symptoms measured using Chalder fatigue questionnaire at baseline, 1 month, 2 months (treatment endpoint) and 3 months (follow-up endpoint)

Key secondary outcome(s)

1. Impact of fatigue on physical function measured using SF-36 physical function at baseline, 1 month, 2 months (treatment endpoint) and 3 months (follow-up endpoint)
2. Quality of life measured using Euroqol Questionnaire at baseline, 1 month, 2 months (treatment endpoint) and 3 months (follow-up endpoint)
3. Severity of TCM spleen deficiency pattern measured using spleen deficiency scale at baseline, 1 month, 2 months (treatment endpoint) and 3 months (follow-up endpoint)
4. Overall health measured using clinical global impression scale at baseline, 2 months (treatment endpoint) and 3 months (follow-up endpoint)

Completion date
11/08/2021

Eligibility

Key inclusion criteria
1. 18-80 years old, both genders
2. Meet the American CDC diagnostic criteria of chronic fatigue syndrome
3. Meet the TCM criteria of spleen deficiency pattern
4. Informed consent

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
80 Years

Sex
All

Total final enrolment
127

Key exclusion criteria
1. Combine with mental disorders
2. Secondary fatigue due to medications or other diseases
3. Combine with severe cardiovascular diseases, cerebrovascular diseases, hepatic diseases, renal diseases, hematological disease, cancer, or other severe primary diseases
4. Pregnant or lactating women
5. Known allergy to ingredients or allergic constitution

6. Mental or legal disability
7. History of antibiotics administration in recent 1 month
8. Drug abuse or others

Date of first enrolment
31/07/2019

Date of final enrolment
30/11/2020

Locations

Countries of recruitment
China

Study participating centre
Longhua Hospital Affiliated to Shanghai University of Traditional Chinese Medicine
725 South Wanping Road
Xuhui District
Shanghai
China
200032

Study participating centre
Yueyang Hospital of Integrated Traditional Chinese and Western Medicine Affiliated to Shanghai University of Traditional Chinese Medicine
110 Ganhe Road
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Study participating centre
Sixth People's Hospital Affiliated to Shanghai Jiao Tong University
600 Yishan Road
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Shanghai Changning Tianshan Traditional Chinese Medicine Hospital
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Jiangyin Hospital of Traditional Chinese Medicine
130 Middle Renming Road
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Sponsor information

Organisation
Longhua Hospital Affiliated to Shanghai University of Traditional Chinese Medicine

ROR
https://ror.org/016yezh07

Funder(s)

Funder type
Government

Funder Name
Shanghai Municipal Health Bureau

Alternative Name(s)
Shanghai Municipal Public Health Bureau

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
China

Results and Publications

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be available upon request from principal investigator Prof. Guang Ji. Individual participant data that underlie the results reported in the final report will become available for sharing after deidentification. Data will be available beginning 6 months and ending 36 months following the final report publication. Researchers should provide a methodologically sound proposal to get data access. And researchers will only be allowed to use the data for the prescribed aims documented in the proposal. Proposals should be directed to Liang Dai (yajlzs123@163.com). To gain access, data requestors will need to sign a data access agreement. Further informed consent may be considered according to the study aims. The shared data will only be allowed to be used by the applicant for scientific studies. No commercial activities are allowed.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		13/04/2024	22/04/2024	Yes	No
Protocol article	protocol	01/10/2019	09/12/2019	Yes	No