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Efficacy and safety of the Xiaoyao pill for improving the clinical symptoms of stagnation of liver qi (chi) and spleen deficiency

Submission date
17/09/2020

Recruitment status
No longer recruiting

Registration date
24/09/2020

Overall study status
Completed

Last Edited
31/05/2024

Condition category
Mental and Behavioural Disorders

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

Plain English summary of protocol

Background and study aims
Symptoms of depression include loss of interest, loss of sleep and appetite, fatigue and inattention. About 322 million people worldwide suffer from depression, accounting for 4.4% of the world's total population. There are about 54.8 million cases in China, accounting for 4.2% of the Chinese population. In Traditional Chinese Medicine (TCM), the Xiaoyao pill is the fundamental prescription for symptoms of stagnation of liver qi and spleen deficiency. The aim of this study is to assess the effects of the Xiaoyao pill for mild to moderate depression and provide clinical evidence for the biological basis of TCM.

Who can participate?
Patients aged 18-65 with mild to moderate depression

What does the study involve?
Participants are randomly allocated to either the Xiaoyao pill group or the placebo group, receiving either Xiaoyao pill or placebo (dummy pill) twice a day for four consecutive weeks. Depression symptoms are measured at the start of the study and after 2 and 4 weeks. Blood and fecal samples are also collected at the start and the end of treatment to further explore the potential mechanism. This study will take some measures to protect patients from serious adverse events.

What are the possible benefits and risks of participating?
The potential benefit is that depression patients with symptoms of stagnation of liver qi and spleen deficiency may have improved symptoms and quality of life from the Xiaoyao pill treatment. No obvious side effects are documented. During the course of treatment it may be identified that there are some adverse reactions for the patient. This study has procedures in place to safeguard patients. Patients at risk will be counselled by their therapists and signposted to specialist services as appropriate.

Where is the study run from?
Beijing University of Chinese Medicine (China)

When is the study starting and how long is it expected to run for?
September 2020 to September 2022

Who is funding the study?
National Natural Science Foundation (China)

Who is the main contact?
Prof. Jiaxu Chen
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Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number

Nil known

Secondary identifying numbers
81630104 (National Natural Science Foundation)

Study information

Scientific Title
Xiaoyao pill for the treatment of stagnation of liver qi and spleen deficiency with depression: a multi-center randomized controlled double-blind trial

Study objectives
The trial aims to assess the therapeutic effects of Xiaoyao pill for mild to moderate depression. The aim is to provide clinical evidence for the biological basis of traditional Chinese medicine (TCM).

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 04/06/2020, Ethics Committee of Beijing University of Chinese Medicine (No. 11, Bei San Huan Dong Lu, Chaoyang District, Beijing,100029, China; +86 (0)10 53911431;bucmyxll@126.com), ref: 2020BZYLL0304

Study design
Multi-centre double-blinded randomized placebo-controlled parallel 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 below to request a patient information sheet

Health condition(s) or problem(s) studied
Mild to moderate depression with symptoms of stagnation of liver qi and spleen deficiency

Interventions
The 108 eligible participants will be allocated to the experimental or placebo arm based on a random lottery. Participants will be required to take the medicine twice daily for four consecutive weeks and the dosage is 9 g twice a day.

The experimental intervention is the Xiaoyao pill. Xiaoyao pills are water honey pills (Z20013060) produced by Jiuzhitang Co., Ltd. The appearance and specifications of the placebo are the same as Xiaoyao pills.

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Xiaoyao pill

Primary outcome measure
Depression with symptoms of stagnation of liver qi and spleen deficiency, assessed using the Hamilton Depression scale (HAMD) at baseline, 1 week, 2 weeks and 4 weeks

Secondary outcome measures
Overall health measured using TCM symptoms Scale at baseline, 1 week, 2 weeks and 4 weeks

Overall study start date
30/09/2020

Completion date
30/09/2022

Eligibility

Key inclusion criteria
1. Meet the Diagnostic Statistics Manual of Mental Disorders (DSM-5) regarding the diagnosis of mild to moderate depression
2. A score between 20 and 35 on HAMD
3. Meet the TCM criteria of liver depression and spleen deficiency syndrome
4. Aged between 16 - 18 years old, both genders
5. Patients agree to participate in this trial and assign the informed consent
6. Capable of reading and follow-up treatment, and permanently live locally

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants

Key exclusion criteria
1. Bipolar depression,treatment-resistant depression and severe suicidal risk
2. History of bipolar disorder, schizophrenia, obvious psychotic symptoms and depression disorder caused by non-addictive substances
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. Inability to finish the compliance test, judge the efficacy and have complete data
6. Involved with any other clinical trial at the time of consent

Date of first enrolment
30/10/2020

Date of final enrolment
30/12/2021

Locations

Countries of recruitment
China

Study participating centre
The First Affiliated Hospital of Jinan University (Guangzhou Overseas Chinese Hospital)
613 W. Huangpu Avenue
Guangzhou
China
510630

Study participating centre
The Affiliated Brain Hospital of Guangzhou Medical University
No.36, Mingxin Road
Fangcun
Liwan District
Guangzhou
China
510370

Study participating centre
Dongfang Hospital (Beijing University of Chinese Medicine Second Affiliated Hospital)
No. 6 Fangxingyuan 1st Block
Fengtai District

Beijing
China
100078

Study participating centre
Beijing Anding Hospital Capital Medical University
5 Ankang Hutong
Xicheng District
Beijing
China
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Study participating centre
Peking University Sixth Hospital
No. 51 Hua Yuan Bei Road
Haidian District
Beijing
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100191

Study participating centre
Tongde Hospital of Zhejiang Province
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310012

Study participating centre
Beijing University of Chinese Medicine Third Affiliated Hospitail
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Study participating centre
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Sponsor type
University/education

Website
http://www.bucm.edu.cn/

Funder(s)

Funder type
Government

Funder Name
National Natural Science Foundation of China

Alternative Name(s)
Chinese National Science Foundation, Natural Science Foundation of China, National Science Foundation of China, NNSF of China, NSF of China, , National Nature Science Foundation of China, Guójiā Zìrán Kēxué Jījīn Wěiyuánhuì, NSFC, NNSF, NNSFC

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
China

Results and Publications

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

Intention to publish date
30/09/2021

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article		04/01/2022	07/11/2023	Yes	No
Results article		20/04/2024	31/05/2024	Yes	No