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Effectiveness and safety of Hongjin Xiaojie Capsule versus waiting list for breast pain

Submission date
13/08/2019

Recruitment status
No longer recruiting

Registration date
18/08/2019

Overall study status
Completed

Last Edited
06/09/2024

Condition category
Signs and Symptoms

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

Plain English summary of protocol

Background and study aims
Breast pain, with different degrees of pain in the breast, belongs to the category of "lump in breast" in traditional Chinese medicine. It mainly includes two types: periodic breast pain and non-periodic breast pain. Cyclical pain is the most common type to date, and the incidence can account for 70% of breast pain. The clinical manifestations are diffused pain or tenderness in one or both breasts, and breast swelling may increase or decrease with the menstrual cycle. It seriously affects the quality of life of women. Hormone therapy is usually used in clinical practice, but the side effects are usually significant, and long-term use may interfere with endocrine regulation. The Chinese herbal medicine Hongjin Xiaojie capsule belongs to Chinese patent medicine. It is known as the "female holy medicine" and has the effect of detumescence and pain, soft firmness and loose knot, promoting blood circulation and removing blood stasis, soothing liver and regulating qi. Hongjin Xiaojie capsule is originated from the century-old minority Yi folk medicine classics, and is widely used in Yi nationality areas, especially in Yunnan province. It was approved as a herbal drug by the China Food and Drug Administration in 1999, and it was included in the Guidelines for Clinical Application of Chinese Medicines in 2017. It is listed as an optional Chinese patent medicine for breast pain. The aim of this study is to evaluate the clinical effectiveness and safety of Chinese patent medicine Hongjin Xiaojie capsule in the treatment of breast pain.

Who can participate?
Premenopausal or perimenopausal women with breast pain aged 18 to 55 years old

What does the study involve?
Participants are randomly allocated into two groups. One group receives Hongjin Xiaojie capsule for three months (not taking the medicine during menstruation). The other group receives no treatment during the first three months. After three months, the participants in the waiting list group can volunteer to take the test medicine for three months.

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 women with breast pain. This may reduce hospital admissions and improve their quality of life. There may be some minor adverse effect associated with this medicine in a few patients.

Where is the study run from?
1. The Third Affiliated Hospital of Beijing University of Chinese Medicine, Beijing, China
2. Beijing Fang Shan District Hospital of Chinese Medicine, Beijing, China
3. Sichuan Second Hospital of Traditional Chinese Medicine, Chengdu, Sichuan, China
4. Shuguang Hospital Affiliated to Shanghai University of Chinese Medicine, Shanghai, China

When is the study starting and how long is it expected to run for?
August 2019 to December 2021 (updated 08/01/2021, previously: December 2020)

Who is funding the study?
Yunnan Yousheng Pharmaceutical Co., Ltd. (China)

Who is the main contact?
1. Jian-ping Liu (Scientific)
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Contact information

Type(s)
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Study information

Scientific Title
Effectiveness and safety of Hongjin Xiaojie Capsule versus waiting list for breast pain: a multi-center, randomized controlled trial

Study objectives
Compared with no treatment, Chinese herbal medicine Hongjin Xiaojie capsule may be effective and safe for relieving breast pain in women.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 31/07/2019; IRB of The Third Affiliated Hospital, Beijing University of Chinese Medicine (No. 51 Xiao Guan Jie, An Ding Men Wai, Chaoyang District, Beijing; Tel: +86 (0)10-52075242; Email: zydsyky@126.com); Approval number: BZYSY-2019KYKTPJ-05

Primary study design
Interventional

Study design
Multicentre randomized clinical trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Breast pain

Interventions
Participants will be randomly allocated into two groups. The method of randomisation: central randomisation run by the leading clinical site (3rd Affiliated Hospital of Beijing University of Chinese Medicine), and the generation of allocation sequence was developed by random number tables.

The treatment group will receive Hongjin Xiaojie capsules for three months (stop taking this medicine during menstruation), 3 times/day
The control (waiting list) group will receive no treatment during the first three months. After

three months, the participants can volunteer to take the tested medicine for three months
The dosage given: 4 capsules/time, three times per day
Co-intervention (analgesic drug) will be allowed if patients feel pain not well controlled

The total duration of follow-up: 24 weeks ± 3 days

Intervention Type
Drug

Phase
Phase IV

Drug/device/biological/vaccine name(s)
Hongjin Xiaojie capsule

Primary outcome(s)
1. The degree of breast pain measured using short-form of McGill questionnaire (SF-MPQ) at baseline, 4 weeks ± 3 days (duration of treatment), 8 weeks ± 3 days (duration of treatment), 12 weeks ± 3 days (end of treatment), 24 weeks ± 3 days (end of follow-up)
2. The duration of pain: the number of days of breast pain during each menstrual cycle measured at baseline, 4 weeks ± 3 days (duration of treatment), 8 weeks ± 3 days (duration of treatment), 12 weeks ± 3 days (end of treatment), 24 weeks ± 3 days (end of follow-up)

Key secondary outcome(s)
1. Breast nodule size: the size of the nodule is determined by both palpation and B-ultrasound at baseline, 12 weeks ± 3 days (end of treatment)
2. Hysteromyoma size (if complicated): abdominal uterus colour ultrasound is used for examination and measurement at baseline, 12 weeks ± 3 days (end of treatment)
3. Menstrual conditions: including menstrual bleeding volume, menstrual cycle, dysmenorrhea, etc, measured at baseline, 4 weeks ± 3 days (duration of treatment), 8 weeks ± 3 days (duration of treatment), 12 weeks ± 3 days (end of treatment), 24 weeks ± 3 days (end of follow-up)
4. Safety outcome indicators:
4.1. General physical examination items measured at baseline, 12 weeks ± 3 days (end of treatment)
4.2. Blood, urine, stool routine samples at baseline, 12 weeks ± 3 days (end of treatment)
4.3. Electrocardiogram, liver and kidney function measured using blood biochemical tests at baseline, 12 weeks ± 3 days (end of treatment)
4.4. Other symptoms and signs other than pain measured using patient diary at 4 weeks ± 3 days (duration of treatment), 8 weeks ± 3 days (duration of treatment), 12 weeks ± 3 days (end of treatment), 24 weeks ± 3 days (end of follow-up)

Completion date
31/12/2021

Eligibility

Key inclusion criteria
1. 18 - 55 years old, female, pre- or peri-menopause
2. Meeting the diagnostic criteria of breast pain; including women with breast nodules, the longest diameter of B-ultrasonic solid nodules ≤2cm or the longest diameter of B-ultrasonic cystic nodules ≤2 cm

3. The number of days of breast pain for each menstrual cycle is equal or longer than 3 days and visual analog scale (VAS) ≥ 4 points; if treated before, the pain symptom could not relieve for three consecutive menstrual cycles or more
4. Women diagnosed as hysteromyoma according to the diagnostic criteria of hysteromyoma will be included
5. The menstrual cycle and the menstrual period are basically regular, and the menstrual cycle is about 28 ± 7 days

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Upper age limit
55 Years

Sex
Female

Total final enrolment
298

Key exclusion criteria
1. Women who are preparing for pregnancy or who are pregnant or lactating
2. Patients with allergic constitution, or allergic to the test drug or its components
3. Breast image report and data system (BI-RADS) classification > level 3
4. Patients with breast malignant tumors, inflammatory diseases and other endocrine diseases (such as pituitary tumors)
5. Taking contraceptives during the trial and using hormonal drugs within the first three months of screening
6. Those who have taken Chinese or Western medicines to treat this disease within 1 month before screening or those who participated in other clinical drug trials
7. Patients with severe primary diseases including cardiovascular, cerebrovascular, liver, kidney and hematopoietic system, or patients with mental illness

Date of first enrolment
01/10/2019

Date of final enrolment
31/10/2021

Locations

Countries of recruitment
China

Study participating centre
The Third Hospital Affiliated to Beijing University of Chinese Medicine
No. 51, Xiaoguan Street outside Andingmen, Chaoyang District
Beijing
China
100029

Study participating centre
Beijing fangshan district hospital of Chinese medicine
No. 151, Chengguan South Street, Fangshan District
Beijing
China
100029

Study participating centre
Sichuan Second Hospital of Traditional Chinese Medicine
No. 20, Sidao Street, Qingyang District
Chengdu
China
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Study participating centre
Shuguang Hospital Affiliated to Shanghai University of Chinese Medicine
No. 185, Pu'an road, Huangpu district
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Sponsor information

Organisation
Yunnan Yousheng Pharmaceutical Co., Ltd

Funder(s)

Funder type
Industry

Funder Name
Yunnan Yousheng Pharmaceutical Co., Ltd

Results and Publications

Individual participant data (IPD) sharing plan
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. Data requests will be directed to Prof Jian-ping Liu at the Centre for Evidence-Based Chinese Medicine, Beijing University of Chinese Medicine, Beijing, China; Tel: +86 (0)10 64286760; Email: Liujp@bucm.edu.cn. Since this trial was sponsored by the pharmaceutical company (Yunnan Yousheng) and there is a contract between the company and the trial institutions, any request of data will need approval through the negotiation of the PI and the company and in accordance with the regulation of ethical and personal privacy policy in China.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article		20/08/2024	06/09/2024	Yes	No
Other unpublished results			07/03/2024	No	No