ISRCTN60424612 https://doi.org/10.1186/ISRCTN60424612

Using a traditional Chinese herbal treatment to reduce period pain related to a mix of cold and heat symptoms

Submission date	Recruitment status	[_] Prospectively registered
13/03/2026	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
17/03/2026	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
16/03/2026	Urological and Genital Diseases	[X] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Public, Scientific, Principal investigator

Contact name
Dr Yuqiong Gao

ORCID ID
https://orcid.org/0009-0002-9177-7407

Contact details
No. 7 Xingyang Road, Danxi Street, Xiangshan County
Ningbo
China
315700
+86 13736088447
Gao_yuqiong59@163.com

Additional identifiers

Study information

Scientific Title
Modified Chaihu Guizhi Ganjiang decoction in treating dysmenorrhea with cold-heat complex pattern: a randomized controlled trial

Study objectives

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 31/07/2024, Xiangshan Hospital of Traditional Chinese Medicine Medical & Health Group (No. 7 Xingyang Road, Danxi Street, Xiangshan County, Ningbo, 315700, China; +86 0574-65655700; xszyy2006@126.com), ref: XZYJ-2024-002

Primary study design
Interventional

Allocation
Randomized controlled trial

Masking
Open (masking not used)

Control
Dose comparison

Assignment
Parallel

Purpose
Treatment

Study type(s)

Health condition(s) or problem(s) studied
Dysmenorrhea

Interventions
This was a prospective randomized controlled study. Seventy patients with dysmenorrhea were recruited from the Xiangshan County Hospital of Traditional Chinese Medicine Healthcare Group between June 2021 and October 2025. Eligible patients were randomly assigned in a 1:1 ratio to the experimental group (oral administration of modified Chaihu Guizhi Ganjiang Decoction) or the control group (oral administration of Ibuprofen Sustained-Release Capsules) using a random number table. The specific randomization scheme was generated by an independent statistician not involved in patient recruitment, intervention, or data collection using SPSS 25.0. The assignments were sealed in sequentially numbered, opaque envelopes. Upon enrollment of an eligible patient, the study coordinator opened the envelope with the corresponding serial number to reveal the group assignment and implement allocation, ensuring allocation concealment. Due to the different nature of the interventions (Chinese herbal decoction vs. Western medicine capsule), blinding of treating physicians and patients was not feasible. However, to reduce measurement bias, blinding was implemented for the researchers (outcome assessors) responsible for collecting primary outcome measures (including VAS score, CMSS score, and TCM syndrome score). Outcome assessors were not involved in treatment administration and remained unaware of patients' group assignments during data collection and

analysis. This study was approved by the Ethics Committee . All participating patients provided written informed consent. This study employed a two-group parallel-design RCT. Sample size estimation was based on the total effective rate post-treatment as the primary evaluation indicator. According to preliminary trial results, the estimated total effective rate was approximately 90% for the experimental group and 75% for the control group. Setting the significance level α = 0.05 (two-tailed test) and statistical power (1-β) = 0.80, and using the sample size calculation formula for comparing two rates, the required sample size per group was approximately 32. Considering potential dropouts and loss to follow-up during the study, a 20% dropout rate was factored in, ultimately determining a sample size of 35 per group, totaling 70 participants.

Intervention Type
Drug

Phase
Not Applicable

Drug/device/biological/vaccine name(s)
administration of modified Chaihu Guizhi Ganjiang Decoction;administration of Ibuprofen Sustained-Release Capsules

Primary outcome(s)
1. Pain severity measured using Visual Analogue Scale pain score at before treatment, after treatment, and at 1-month follow-up

2. Traditional Chinese medicine syndrome severity measured using Traditional Chinese medicine syndrome score based on the Guiding principles for clinical research of new Chinese medicines (Trial) at before treatment, after treatment, and at 1-month follow-up

3. Menstrual symptom severity and duration measured using COX Menstrual Symptom Scale score at before treatment, after treatment, and at 1-month follow-up

4. Overall clinical effectiveness measured using effective rate calculated from the percentage reduction in traditional Chinese medicine syndrome score at before treatment, after treatment, and at 1-month follow-up

Key secondary outcome(s))

Completion date
13/02/2025

Eligibility

Key inclusion criteria
1. Meeting the above Western medicine diagnostic and TCM pattern differentiation criteria
2. Regular menstrual cycles
3. No hormonal therapy in the preceding three months, and no use of other medications for dysmenorrhea one month prior to or during the treatment period
4. Voluntary participation and provision of signed informed consent

Healthy volunteers allowed

No

Age group
Adult

Lower age limit
18 years

Upper age limit
40 years

Sex
Female

Total final enrolment
70

Key exclusion criteria
1. Presence of an intrauterine device
2. Age <18 or >40 years, or history of irregular menstruation
3. Comorbid severe diseases of vital organs (heart, liver, kidney, brain, etc.)
4. History of allergy to the study medications
5. History of mental illness
6. Treatment history for the condition within the past 2 months
7. Women planning pregnancy, pregnant, or lactating

Date of first enrolment
01/01/2024

Date of final enrolment
01/01/2025

Locations

Countries of recruitment
China

Sponsor information

Organisation
Xiangshan Hospital of Traditional Chinese Medicine Medical & Health Group

Funder(s)

Funder type

Funder Name
Investigator initiated and funded

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary
Not expected to be made available