

A randomised placebo-controlled trial of a traditional chinese herbal formula in the treatment of primary dysmenorrhoea

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| Submission date 03/10/2002 | Recruitment status No longer recruiting | <input checked="" type="checkbox"/> Prospectively registered |
| Registration date 03/10/2002 | Overall study status Completed | <input type="checkbox"/> Protocol |
| Last Edited 03/10/2007 | Condition category Urological and Genital Diseases | <input type="checkbox"/> Statistical analysis plan |
| | | <input checked="" type="checkbox"/> Results |
| | | <input type="checkbox"/> Individual participant data |

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

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Additional identifiers

Protocol serial number

N/A

Study information

Scientific Title

Acronym

FADD (Four-Agents-Decoction for Dysmenorrhoea)

Study objectives

Added as of 23/04/07:

Four-Agents-Decoction (Si Wu Tang) is effective in treating primary dysmenorrhoea.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Added as of 23/04/07:

Approval received from the Human Ethics Committee, National Health Research Institutes; EC9103001(02/20/2002); EC9106001(11/11/2002); EC0930306 (04/27/2004).

Study design

Randomised controlled trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Primary dysmenorrhea

Interventions

Two groups: four-agents decoction and placebo, both are in capsule form.

Added as of 23/04/07:

Two groups: Four-Agents-Decoction (Si Wu Tang) and placebo, both are in capsule form.

Intervention:

This Four-Agents-Decoction (Si Wu Tang) will be custom-made with raw materials prepared according to the original pharmacopoeia and decocted by water extraction in 1:13 ratio from single batched roots of the four plants in equal proportions:

1. Prepared Radix Rehmanniae praeparata
2. Radix Angelicae sinensis
3. Radix Paeoniae alba, and
4. Rhizoma Ligustici chuanxiong

Each capsule contains approximately 500 mg of granules from concentrated decoction, and this is sealed and secured with a band at the interface by a capsule supply company to ensure concealment of the aroma from the materials.

Control:

The identical looking placebo capsules are filled with a powder mixture of cornstarch and caramel. Regimens of five capsules are packaged in aluminum packets for easier handling and to prevent Four-Agents-Decoction (Si Wu Tang) from moisture exposure.

Clinic visit number and case number are to be marked on each packet in both text and bar code. The dosage is 15 capsules daily for five days from the onset of bleeding or pain determined after taking considerations:

1. Habitual usages provided from the three surveys
2. Literature reports
3. A comparison of the concentrations of two indices, paeoniflorin and ferulic acid, in a one-day dose of a commercially available powder with the decoction made from raw materials
4. Information from the studys traditional Chinese medicine physicians, and
5. Input from the studys leading gynaecologist.

Ibuprofen tablet (400 mg), four times daily for three days, is provided for unbearable menstrual pain after holding it off. The participants will record the pain intensity they experience right before taking ibuprofen, the intake of all drugs, the use of other remedies, the amount of collected menstrual blood for evaluating menorrhagia if any, and the number of days missing work or school on an online diary. The intervention duration will be three menstrual cycles.

Intervention Type

Drug

Phase

Not Specified

Drug/device/biological/vaccine name(s)

Four-Agents-Decoction (Si Wu Tang)

Primary outcome(s)

Added as of 23/04/07:

Pain intensity evaluated by an online unmarked Visual Analogue Scale (VAS) of one to ten cm matched 1000 scales in our database for the first five days of each menstrual cycle.

Key secondary outcome(s))

Added as of 23/04/07:

Uterine artery pulsatility index measured by study gynecologists.

Completion date

16/07/2004

Eligibility**Key inclusion criteria**

College women aged 18 years and older suffering from menstrual pain with no pathological findings.

Added as of 23/04/07:

1. College women aged 18 years and older suffering from menstrual pain with no pathological findings

2. Cycles lasting 21 to 35 days with the actual menses periods lasting three to seven days, and having at least four consecutive painful periods in the past six months with the pain starting one day before or on the day of onset of bleeding

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

Key exclusion criteria

Added as of 23/04/07:

1. Taking oral contraceptive pills
2. Unwilling to refrain from sexual activity during the study
3. Having had severe gastrointestinal, gynaecological or autoimmune diseases, or gynaecological surgery, including pregnancy

Date of first enrolment

02/01/2003

Date of final enrolment

16/07/2004

Locations**Countries of recruitment**

Taiwan

Study participating centre

Division of Clinical Research

Zhunan, Miaoli County

Taiwan

35053

Sponsor information

Organisation

National Health Research Institutes (Taiwan)

ROR

<https://ror.org/02r6fpx29>

Funder(s)

Funder type

Government

Funder Name

Intramural funding, National Health Research Institutes (Taiwan)

Funder Name

Added as of 23/04/07:

Funder Name

A supplemental grant from the Department of Health and The Office of National Science and Technology Program for Biotechnology and Pharmaceuticals (Taiwan)

Results and Publications

Individual participant data (IPD) sharing plan**IPD sharing plan summary**

Not provided at time of registration

Study outputs

| Output type | Details | Date created | Date added | Peer reviewed? | Patient-facing? |
|---------------------------------|---------|--------------|------------|----------------|-----------------|
| Results article | Results | 15/08/2007 | | Yes | No |