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

Submission date
03/10/2002

Recruitment status
No longer recruiting

Registration date
03/10/2002

Overall study status
Completed

Last Edited
03/10/2007

Condition category
Urological and Genital Diseases

[X] Prospectively registered
[_] Protocol
[_] Statistical analysis plan
[X] Results
[_] 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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers

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

Secondary study design
Randomised controlled trial

Study setting(s)
Not specified

Study type(s)
Treatment

Participant information sheet

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-Dcoction (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 concoctioned 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 measure
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.

Secondary outcome measures
Added as of 23/04/07:
Uterine artery pulsatility index measured by study gynecologists.

Overall study start date

02/01/2003

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

Age group
Adult

Lower age limit
18 Years

Sex
Female

Target number of participants
78 (added as of 23/04/2007)

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)

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35 Keyan Road
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Sponsor type
Government

Website
http://www.nhri.org.tw

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

Publication and dissemination plan
Not provided at time of registration

Intention to publish date

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