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Effects of a Gyejibongnyeong-hwan on dysmenorrhea caused by blood stagnation

Submission date	Recruitment status	[_] Prospectively registered
19/04/2010	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
30/04/2010	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
07/11/2013	Urological and Genital Diseases	

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
CCRG_08_03

Study information

Scientific Title
Effects of a Gyejibongnyeong-hwan on dysmenorrhea caused by blood stagnation: a randomized, double-blinded, placebo-controlled, multicenter study

Study objectives

Gyejibongnyeong-hwan reduces dysmenorrhea caused by blood stagnation more than placebo control.

As of 21/04/2011 the anticipated end date for this trial has been extended from 30/06/2010 to 30/06/2011.

Ethics approval required
Old ethics approval format

Ethics approval(s)
1. Institutional Review Board (IRB) of Kyung Hee Oriental Medical Center approved on the 18/08/2008 (ref: KOMC IRB 2008-07)
2. IRB of Wonkwang University Sanbon oriental medical center approved on the 24/02/2009 (ref: WONSBHB IRB 2009-02)
3. IRB of Kyungwon Gil Oriental Medical Hospital approved on the 02/02/2009 (ref: 09-101)

Primary study design
Interventional

Study design
Randomised double-blind parallel group, placebo-controlled trial phase IV study

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Dysmenorrhea (menstrual pain) caused by blood stagnation

Interventions
Patients will be randomised to receive:
1. Gyejibongnyeong-hwan, a Korean herbal remedy consisting of Cinnamomi ramulus, Poria, Moutan cortex, Persicae semen (peach seed) and Paeoniae radix. 1200 mg/day (400 mg x 3 daily)
2. Placebo control (x 3 daily)
Participants will receive the intervention for approx 8 weeks (two menstrual cycles) and be followed on week 4 and 12 after the end of the treatment. These times will vary depending on the duration of the period/cycle.
Participants will visit six times, screening, visit 1 (week 0), visit 2 (week 4), visit 3 (week 8), visit 4 (week 12), visit 5 (week 20).
The total duration of the trial will be 20 weeks.

Intervention Type
Other

Phase
Phase IV

Primary outcome(s)
Pain, assessed by Visual Analogue Scale (VAS), measured at screening, baseline and weeks 4, 8, 12 and 20

Key secondary outcome(s)

1. Blood Stagnation Scale (based on Korean Medicine), measured at screening, baseline and weeks 4 and 8
2. Quantity of pain killer pills during period, recorded at screening, baseline and weeks 4, 8, 12 and 20
3. Short Form McGill Pain Questionnaire, measured at screening, baseline and weeks 4, 8, 12 and 20
4. Cox Menstrual Symptom Scale, measured at screening, baseline and weeks 4, 8, 12 and 20
5. Heart rate variability (HRV) outcome, measured at screening, baseline and weeks 4 and 8

Completion date
30/06/2011

Eligibility

Key inclusion criteria
1. Female aged 18 to 35 years
2. Women with a period cycle of 30 ± 3 days during last 3 months
3. Women who have menstrual pain (dysmenorrhea) over 6 degrees by Visual Analogue Scale (VAS)
4. Women who are diagnosed with blood stagnation by two oriental medical gynaecologic specialists
5. Given written informed consent form
6. Given written informed consent form of genetic study

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 Years

Sex
Female

Key exclusion criteria
1. Women who have major neuro-psychiatric disorder or have history of major neuro-psychiatric disorder (schizophrenia, epilepsy, alcohol abuse, anorexia etc)
2. Women who are planning to have baby or do not agree to use appropriate contraception (oral pill, hormone contraception, intrauterine device, condom etc)
3. Women who are taking anti-depressant, anti-serotonin barbiturate, psychotropic drugs

Date of first enrolment
19/05/2009

Date of final enrolment

30/06/2011

Locations

Countries of recruitment
Korea, South

Study participating centre
1 Hoegi-dong
Seoul
Korea, South
130-701

Sponsor information

Organisation
Korea Health Industry Development Institute (South Korea)

ROR
https://ror.org/00fdzyk40

Funder(s)

Funder type
Research organisation

Funder Name
Korea Health Industry Development Institute (South Korea)

Alternative Name(s)
KHIDI

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
Korea, South

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	01/01/2013		Yes	No
Protocol article	protocol	05/01/2012		Yes	No