Analgesic effect of acupuncture compared with sham acupuncture in primary dysmenorrhoea: AAEPD-I

Submission date 29/10/2007	Recruitment status No longer recruiting	[X] Prospectively registered
		☐ Protocol
Registration date	Overall study status	Statistical analysis plan
08/11/2007	Completed	[X] Results
Last Edited 04/07/2011	Condition category Urological and Genital Diseases	[] Individual participant data
U4/U///UII	Urological and Genical Diseases	

Plain English summary of protocol

Not provided at time of registration

Contact information

Type(s)

Scientific

Contact name

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Additional identifiers

Protocol serial number 2006CB504503

Study information

Scientific Title

Analgesic effect of acupuncture compared with sham acupuncture in primary dysmenorrhoea: a multicentre, randomised, controlled clinical trial

Acronym

AAEPD-I (Acupuncture Analgesia Effect in Primary Dysmenorrhoea-I)

Study objectives

Some recent Randomised Controlled Trials (RCTs) suggested that acupuncture was no more effective than sham acupuncture. Traditional Chinese medicine uses acupuncture of acupoint Sanyinjiao (SP6) to relieve pain of primary dysmenorrhoea. The present trial was to evaluate the point specificity of analgesia effect of acupuncture at SP6 in primary dysmenorrhoea.

A related trial "Analgesic effect of acupuncture compared with sham acupuncture in primary dysmenorrhoea: AAEPD-II" is registered with ISRCTN24863192.

Ethics approval required

Old ethics approval format

Ethics approval(s)

Ethics approval received from the Medical Ethical Committee of the Beijing University of Traditional Chinese Medicine on the 22nd October 2007 (ref: 200710).

Study design

Multicentre randomised controlled clinical trial

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Primary dysmenorrhoea

Interventions

- 1. Acupuncture
- 2. Sham acupuncture
- 3. Waiting list control

Acupuncture and sham acupuncture were administered once-daily for 3 days with acupuncture at Sanyinjiao (SP6) that was specifically designed to treat primary dysmenorrhoea, or 1 of 2 sham acupuncture treatments: acupuncture for an unrelated acupoint (Xuanzhong, GB39), or needle insertion at non-acupoint locations (lateral side of lower leg, 3 inches above the tip of external malleolus, 1.5 inches behind anterior crest of the bibia).

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

- 1. The VAS score for pain at baseline, 5, 10, 30, and 60 minutes after the first intervention
- 2. Cox Retrospective Symptom Scale (RSS) during 3 menstrual cycles (before the treatment, during the treatment, and in 1 subsequent cycle after intervention)
- 3. Verbal Rating Scale (VRS) during 3 menstrual cycles (before the treatment, during the treatment, and in 1 subsequent cycle after intervention)

Key secondary outcome(s))

- 1. Pain (as measured by VAS score) was also used as a secondary outcome at other time points
- 2. The changes of assigned analgesic medication usage that each participant reported using, and proportion of participants in each group who were using analgesics in addition to their assigned treatment

Completion date

01/10/2008

Eligibility

Key inclusion criteria

- 1. Women aged 18 to 30 years
- 2. A history of regular menstruation (28-day cycle +/- 7 days)
- 3. Primary dysmenorrhoea (onset greater than or equal to 3 years after menarche)
- 4. Menstrual cramping pain of moderate or severe intensity, varying from 4.0 to 10.0 on the Visual Analogue Scale (VAS), and for at least 6 months before study entry
- 5. Not pregnant
- 6. Good general health
- 7. Agree to refrain from the use of any analgesics 24 hours before the first intervention
- 8. Provide written informed consent prior to enrolment

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Lower age limit

18 years

Sex

Female

Key exclusion criteria

- 1. Dysmenorrhoea secondary to organic pathology
- 2. A history of term pregnancy or possible current pregnancy
- 3. Severe gastrointestinal, gynaecological or autoimmune diseases, or gynaecological surgery

Date of first enrolment

Date of final enrolment 01/10/2008

Locations

Countries of recruitmentChina

Study participating centre 11 Bei San Huan Dong Lu Beijing China 100029

Sponsor information

Organisation

Ministry of Science and Technology (China)

ROR

https://ror.org/027s68j25

Funder(s)

Funder type

Government

Funder Name

Ministry of Science and Technology (China) - National Basic Research Programme (ref: 2006CB504503)

Results and Publications

Individual participant data (IPD) sharing plan

IPD sharing plan summary

Not provided at time of registration

Study outputs

Output typeDetailsDate createdDate addedPeer reviewed?Patient-facing?Results articleresults01/02/2011YesNo