

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

Submission date 29/10/2007	Recruitment status No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered
Registration date 08/11/2007	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 04/07/2011	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

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

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 tibia).

Intervention Type

Other

Phase

Not Specified

Primary outcome measure

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)

Secondary outcome measures

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

Overall study start date

11/11/2007

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

Age group

Adult

Lower age limit

18 Years

Sex

Female

Target number of participants

200

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

11/11/2007

Date of final enrolment

01/10/2008

Locations**Countries of recruitment**

China

Study participating centre

11 Bei San Huan Dong Lu

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Sponsor information**Organisation**

Ministry of Science and Technology (China)

Sponsor details

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Sponsor type

Government

Website

<http://www.most.gov.cn/eng/index.htm>

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

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	01/02/2011		Yes	No