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

Submission date	Recruitment status	[X] Prospectively registered
29/10/2007	No longer recruiting	[_] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
08/11/2007	Completed	[X] Results
Last Edited	**Condition category**	[_] Individual participant data
04/07/2011	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

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 bibia).

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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100029

Sponsor information

Organisation
Ministry of Science and Technology (China)

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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