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

| Submission date | Recruitment status | [_] Prospectively registered |
|---|---|---|
| 15/11/2008 | No longer recruiting | [_] Protocol |
| **Registration date** | **Overall study status** | [_] Statistical analysis plan |
| 11/12/2008 | Completed | [X] Results |
| **Last Edited** | **Condition category** | [_] Individual participant data |
| 20/02/2015 | 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 multi-centre randomised controlled clinical trial-II

### Acronym
AAEPD-II (Acupuncture Analgesia Effect in Primary Dysmenorrhoea-II)

### Study objectives
Some recent randomised controlled trials (RCTs) suggested that acupuncture was no more effective than sham acupuncture. Because of small sample size in the previous study (50 patients in each arm) (ISRCTN84496835), we have a design for a larger sample of trial to evaluate the point specificity of analgesic effect of acupuncture at SP6 in primary dysmenorrhoea. For the primary outcome measure the Visual Analogue Scale (VAS) score for pain at baseline and 30 minutes after the first intervention, the previous study (ISRCTN84496835) suggested a 47.58% improvement for acupoint group, compared with 40.71% for non-acupoint group. We used these findings as the basis for our power calculation. At 5% significance and 80% power, 145 patients are required in each arm. Taking into consideration a 15% dropout rate, at least 167 patients in each arm are needed.

### Ethics approval required
Old ethics approval format

### Ethics approval(s)
Medical Ethics Committee of the Beijing University of Chinese Medicine, approved on 10/11 /2008

### Study design
Multi-centre 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
Not available in web format, please use the contact details below to request a patient information sheet

### Health condition(s) or problem(s) studied

Primary dysmenorrhoea

### Interventions
1. Acupuncture
2. Sham acupuncture

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 Applicable

### Primary outcome measure
1. 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, before the second intervention, before the third intervention, and during 3 menstrual cycles
2. The changes in assigned analgesic medication usage that each participant reported using during 2 menstrual cycles (during the treatment and in 1 subsequent cycle after intervention), and proportion of participants in each group who were using analgesics in addition to their assigned treatment during 2 menstrual cycles (during the treatment and in 1 subsequent cycle after intervention)

### Overall study start date
01/12/2008

### Completion date
31/12/2009

## 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 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
501

### 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
4. They have previously received acupuncture (to maximize blinding)

### Date of first enrolment
01/12/2008

### Date of final enrolment
31/12/2009

## Locations

### Countries of recruitment
China

### Study participating centre
**Beijing University of Chinese Medicine**
Beijing
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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 |
| Results article | results | 21/02/2014 | | Yes | No |

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| Results article | results | 01/06/2014 | Yes | No |