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

Submission date	Recruitment status  No longer recruiting	Prospectively registered	
15/11/2008		☐ Protocol	
Registration date	Overall study status	Statistical analysis plan	
11/12/2008	Completed	[X] Results	
<b>Last Edited</b> 20/02/2015	Condition category Urological and Genital Diseases	[] Individual participant data	

#### 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 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

#### Study type(s)

Treatment

#### 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(s)

- 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)

#### Key secondary outcome(s))

- 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)

#### 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** 

#### 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
- 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 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 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
Results article	results	01/06/2014	Yes	No
Participant information sheet	Participant information sheet	11/11/2025 11/11/2025	No	Yes