

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

Submission date 15/11/2008	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered
Registration date 11/12/2008	Overall study status Completed	<input type="checkbox"/> Protocol
Last Edited 20/02/2015	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

Contact name
Prof Jiang Zhu

Contact details
Beijing University of Chinese Medicine
11 Bei San Huan Dong Lu
Chao Yang District
Beijing
China
100029
+86 (0)10 8456 0099
603005@bucm.edu.cn

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 tibia).

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