

Effects of acupuncture on hot flushes in perimenopausal and post-menopausal women: a multicentre randomised clinical trial

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| Submission date 09/09/2008 | Recruitment status No longer recruiting | <input type="checkbox"/> Prospectively registered |
| Registration date 18/09/2008 | Overall study status Completed | <input checked="" type="checkbox"/> Protocol |
| Last Edited 30/12/2020 | Condition category Urological and Genital Diseases | <input type="checkbox"/> Statistical analysis plan |
| | | <input type="checkbox"/> Results |
| | | <input type="checkbox"/> Individual participant data |
| | | <input type="checkbox"/> Record updated in last year |

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

KE0801

Study information

Scientific Title

Effects of acupuncture on hot flushes in peri-menopausal and post-menopausal women: a multicentre randomised clinical trial

Study objectives

Acupuncture could reduce the frequency and severity of hot flushes and alleviate menopausal symptoms in peri-menopausal and post-menopausal women.

Ethics approval required

Old ethics approval format

Ethics approval(s)

1. The Research Ethics Board of Dongguk International Hospital on 2nd July 2008
2. East-West Neo Medical Centre, Kyung Hee University on 17th June 2008
3. Dong Eui Medical Centre, Dong Eui University on 5th June 2008
4. Semyung University Hospital on 10th June 2008

Study design

Multicentre randomised controlled trial with two parallel arms

Primary study design

Interventional

Study type(s)

Treatment

Health condition(s) or problem(s) studied

Hot flushes

Interventions

Arm A : Standardised traditional korean acupuncture plus usual care

Arm B : Usual care alone

Arm A receives acupuncture 3 times/week, total 12 sessions for 4 weeks, and will be followed up 4 weeks after finishing acupuncture treatment. Total duration will be 8 weeks (4 weeks treatment plus 4 weeks follow up).

Arm B receives no acupuncture treatments during 4 weeks. After 4 weeks, if they want to take the acupuncture treatment, the same treatment will be provided. But we will not use this data for the current trial. Total duration will be 4 weeks (4 weeks usual care alone).

Both groups maintain usual care during the trial. Use of over-the-counter (OTC) drugs for managing usual symptoms like episodic colds, headaches and dyspepsia, and of some supplements for self-care on menopausal symptoms will be permitted as usual care. All participants will be asked to notice any other attempts of receiving new treatments or cares for their health condition before employing them to avoid the protocol violation.

Intervention Type

Other

Phase

Not Specified

Primary outcome(s)

Hot flush score: calculated by multiplying daily frequency and severity (0 : none, 1: mild, 2: moderate, 3: severe, 4: very severe) of hot flushes. Frequency and severity of hot flushes will be derived from self-reported daily logs, and data will be collected every 1 week. Participants are required to fill the diary during the treatment and follow-up phases.

Key secondary outcome(s)

Menopause Rating Scale (MRS): measured at baseline, 2 and 4 weeks after randomisation in both group. Additional measure at 6 and 8 weeks after randomisation will be conducted in Arm A during follow-up phase.

Completion date

01/11/2008

Eligibility

Key inclusion criteria

1. Peri-menopausal or post-menopausal women within 45 and 60 years old
2. Average daily hot flush scores greater than 10 for last one week at screening visit

Participant type(s)

Patient

Healthy volunteers allowed

No

Age group

Adult

Sex

Female

Key exclusion criteria

1. Participants under serious medical conditions (like uncontrolled hypertension, diabetes mellitus needed to be controlled by insulin injection, etc.)
2. Any type of thyroid dysfunction
3. History of past or current malignant tumour
4. Severe dyslipidaemia
5. Other infectious diseases or systemic diseases which is inadequate for acupuncture treatment
6. Use of any hormones, antidepressants, gabapentin, selective serotonin reuptake inhibitor (SSRI) and sedatives
7. Use of black cohosh and human placenta extracts
8. Any additional acupuncture treatment, herb prescription, therapeutic performance by other traditional Korean medicine (TKM) doctor during the study
9. Night-workers

Date of first enrolment

15/06/2008

Date of final enrolment

01/11/2008

Locations

Countries of recruitment

Korea, South

Study participating centre

Department of Medical Research

Daejeon

Korea, South

305811

Sponsor information

Organisation

Korea Institute of Oriental Medicine (South Korea)

ROR

<https://ror.org/005rpmt10>

Funder(s)

Funder type

Research organisation

Funder Name

Korea Institute of Oriental Medicine (South Korea) - Acupuncture, Moxibustion and Meridian Research Project (ref: K08010)

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? |
|----------------------------------|----------------|---------------------|-------------------|-----------------------|------------------------|
| Protocol article | protocol | 03/12/2008 | 30/12/2020 | Yes | No |