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

Submission date
09/09/2008

Recruitment status
No longer recruiting

Registration date
18/09/2008

Overall study status
Completed

Last Edited
30/12/2020

Condition category
Urological and Genital Diseases

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[_] Results
[_] Individual participant data
[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

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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

Primary study design
Interventional

Study design
Multicentre randomised controlled trial with two parallel arms

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