ISRCTN49335612 https://doi.org/10.1186/ISRCTN49335612

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

Submission date	Recruitment status	[_] Prospectively registered
09/09/2008	No longer recruiting	[X] Protocol
Registration date	**Overall study status**	[_] Statistical analysis plan
18/09/2008	Completed	[_] Results
Last Edited	**Condition category**	[_] Individual participant data
30/12/2020	Urological and Genital Diseases	[_] Record updated in last year

Plain English summary of protocol
Not provided at time of registration

Contact information

Type(s)
Scientific

Contact name
Mr Kun Hyung Kim

Contact details
Department of Medical Research
Korea Institute of Oriental Medicine
483 Expo-ro
Yuseong-gu
Daejeon
Korea, South
305811
+82 (0)42 868 9269
pdchrist@kiom.re.kr

Additional identifiers

EudraCT/CTIS number

IRAS number

ClinicalTrials.gov number

Secondary identifying numbers
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

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

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
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 measure
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.

Secondary outcome measures
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.

Overall study start date
15/06/2008

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

Age group
Adult

Sex

Female

Target number of participants
180

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)

Sponsor details
c/o Sun-Mi Choi
483 Expo-ro
Yuseong-gu

Daejeon
Korea, South
305811
+82 (0)42 868 9485
smchoi@kiom.re.kr

Sponsor type
Research organisation

Website
http://www.kiom.re.kr/index.jsp

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

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