Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of Auricular acupuncture on reduction of blood pressure in patients with chronic essential hypertension: A randomized sham-controled clinical trial

Protocol summary

Study aim

Measurement of changes in systolic and diastolic blood pressure before and after intervention and after 1months followup after ear acupuncture intervention

Design

Randomized, sham-controlled , parallel group trial with blinded outcome assessment. Randomization was centralized and computerized with concealed randomization sequence carried out by an external technician.sample volume was60 and each group had 30 patients.

Settings and conduct

.Before conducting the study, the purpose and procedure of the study were explained to the subjects and a written consent for the study participation was obtained.شارئ180/120زیر The subjects of this study were recruited from Mashhad university of medical science health centers in Mashhad, Iran. The inclusion criteria were adult people over 18 years old with essential hypertension,who had not have blood pressure more than 180/120mmhg in preceding month , and not taking acupuncture or participating in another study. The exclusion criteria were those who had cardiovascular complication such as heart failure or stoke,other significant diseases such as liver or renal disease,taking drugs for seizure or cancer,women who were pregnant or breastfeeding,

Participants/Inclusion and exclusion criteria

Inclusion criteria :1.age>=18. 2.Essential hypertension(not secondary) 3..BP<180\120 in preceding month Exclusion criteria:1. cardiovascular complications 2.accompanying diseases such as kidney,lung,liver,autoimmune diseases and cancer 3. taking other drugs such as anticoagulant or seizure drugs.

Intervention groups

intervention group are patients with essential hypertension who receive. needle- containing adhesive tapes . placebo group are patients with essential hypertension who receive. needle- free adhesive tapes .

Main outcome variables

Systolic blood pressure,diastolic blood pressure,mean blood pressure

General information

Reason for update

change in method which includes substitution of needle containing tages ,so no need to pressure on tages because needle stimulates the points and in this method patients will be completely blinded.

Acronym

IRCT registration information

IRCT registration number: **IRCT20110809007265N13**
Registration date: **2022-08-27, 1401/06/05**
Registration timing: **registered_while_recruiting**

Last update: **2024-01-09, 1402/10/19**
Update count: **1**

Registration date

2022-08-27, 1401/06/05

Registrant information

Name

Hoda Azizi

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date
2022-08-21, 1401/05/30
Expected recruitment end date
2022-09-21, 1401/06/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of Auricular acupuncture on reduction of blood pressure in patients with chronic essential hypertension: A randomized sham-controled clinical trial

Public title
Evaluation of ear acupuncture on reduction of blood pressure
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age equal or more than 18 Essential hypertension (not secondary) blood pressure less than 180/120 mmHg in preceding month
Exclusion criteria:
Organ disease such as heart, lung ,renal disease … cardiovascular complications taking drug for cancer .seizure participation in other trials taking acupuncture pregnant or breast-feeding
Age
From **18 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
This is simple randomization .Each patient takes an concealed envelope containing letter A or B for true or sham group.These envelopes were provided by statistic analyzer of the study. The main researcher pastes either true needle tag or sham needle-free tag to the patients based on letter A or B.These tags are apparently identical.
Blinding (investigator's opinion)
Double blinded
Blinding description
The patients,health personnel who check BP and outcomes,research analyzer and data gathering person are blinded but the main researcher who inserts adhesive tapes is not blinded.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Mashhad University of Medical Sciences
Street address
Qorashi building, Daneshgah Street
City
Mashhad
Province
Razavi Khorasan
Postal code
91357345
Approval date
2022-07-19, 1401/04/28
Ethics committee reference number
IR.MUMS.REC.1401.122

Health conditions studied

1

Description of health condition studied
Essential hypertension
ICD-10 code
I10
ICD-10 code description
Essential (primary) hypertension

Primary outcomes

1

Description
Systolic blood pressure,Diastolic blood pressure,mean blood pressure
Timepoint
Before and after intervention,at the end of 1 month followup
Method of measurement
Digital arm sphygmomanometer

Secondary outcomes

1

Description
Quality of life
Timepoint
Before and after the intervention, at the end of 1 month follow up
Method of measurement
Questionary

2

Description
Change in medication dose
Timepoint
Before and after the intervention, at the end of 1 months follow up
Method of measurement
study checklist

Intervention groups

1

Description
After randomization,standard SF-36questionarie filled out by patients and blood pressure measured by digital arm sphygmomannometer.4 adhesive tape containg1mm needle in its center are pasted to specific ear points(shenmen,superior triangular fossa,Chinese liver and heart)on right ear.7 days later patients will come back and tapes removed and blood pressure be measured and new tapes pasted on the points on left ear.4 times (4weeks) will be dine again with tapes 2weeks on right and 2weeks on left ear.at end of last session SF-36questionarie will be filled by patients.after one month patients will come back for follow up and blood pressure will be measured and the questionnaire will be filled.
Category
Treatment - Other

2

Description
After randomization,standard SF-36 questionarie filled out by patients and blood pressure measured by digital arm sphygmomannometer.4 adhesive tape free of needle are pasted to specific ear points(shenmen,superior triangular fossa,Chinese liver and heart) on right ear. Seven days later patients will come back and tapes removed and blood pressure be measured and new tapes pasted on the points on left ear.Four times (4 weeks) will be done again with tapes 2 weeks on right and 2 weeks on left ear.at end of last session SF-36 questionarie will be filled by patients. After one month patients will come back for follow up and blood pressure will be measured and the questionnaire will be filled.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital
Full name of responsible person
Hoda Azizi
Street address
Daneshgah Street
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Rahim Firoyzi bostanabad

Position
Ph.D.candidate

Latest degree
Specialist

Other areas of specialty/work
Cardiology

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Person responsible for scientific inquiries

Contact

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Hoda azizi

Position
Associate professor

Latest degree
Ph.D.

Other areas of specialty/work
Medical Education

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Person responsible for updating data

Contact

Name of organization / entity
Mashhad University of Medical Sciences

Full name of responsible person
Dr Hoda Azizi

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Assiciated Professor of Acupuncture

Latest degree
Ph.D.

Other areas of specialty/work
Others

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
It depends on the written permission of patients who participate in this study

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available