

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

The effect of Auricular acupuncture on reduction of blood pressure in patients with chronic essential hypertension: A randomized sham-controlled 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.شار. 180/120 زیر 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 $\geq$ 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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+98 51 1855 2188

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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-controlled 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-36 questionnaire filled out by patients and blood pressure measured by digital arm sphygmomanometer. 4 adhesive tape containing 1mm 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 (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 questionnaire 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 questionnaire filled out by patients and blood pressure measured by digital arm sphygmomanometer. 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 questionnaire 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

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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

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Contact

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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