Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the effect of Electro Acupuncture and Laser Acupuncture in the treatment of patients with mild high blood pressure

Protocol summary

Study aim
Comparing the effect of electro acupuncture and laser acupuncture in the treatment of patients with mild high blood pressure

Design
The clinical trial has a control group, a blind strain, randomized on 30 patients, and the rand function of Excel software is used for randomization

Settings and conduct
The place of study is in the research center clinic of Semnan University of Medical Sciences. The method of doing the work is that the patients are divided into 3 groups, in which 1 intervention group electro acupuncture on 10 specified points and in the other group laser acupuncture on 10 specified points like The previous group is applied and no intervention is received in the control group. Blood pressure is evaluated by a Holter device before and after the intervention and by a digital Barometer before and after the first session and a general question about the patient's blood pressure status is performed in the 1 month follow-up and the results are analyzed. The study is a blinded strain.

Participants/Inclusion and exclusion criteria
Patients with mild hypertension (stage 1), i.e., systolic blood pressure between 140 and 159 mm Hg and diastolic blood pressure between 90 and 99 mm Hg, who have been receiving medical treatment for high blood pressure for more than one year. Patients should not take more than one type of blood pressure medication per day, and also patients should not have high blood pressure secondary to other diseases.

Intervention groups
The intervention of electro acupuncture and laser acupuncture is applied in 2 treatment groups, and in the control group, the patients do not receive any intervention and only take their medicine. in both intervention groups, patients continue to take their medicine.

Main outcome variables
Examination of systolic and diastolic blood pressure and heart rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160808029264N16**
Registration date: **2023-04-12, 1402/01/23**
Registration timing: **prospective**

Last update: **2023-04-12, 1402/01/23**
Update count: **0**

Registration date
2023-04-12, 1402/01/23

Registrant information

Name
Rasool Bagheri

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 23 3344 1022

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rasool.bagheri@ymail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-05-22, 1402/03/01

Expected recruitment end date
2023-12-21, 1402/09/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of the effect of Electro Acupuncture and Laser Acupuncture in the treatment of patients with mild high blood pressure

Public title
Comparison of the effect of Electro Acupuncture and Laser Acupuncture in the treatment of patients with mild high blood pressure

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Patients with mild hypertension (stage 1) , i.e., systolic blood pressure between 140 and 159 mmHg and diastolic blood pressure between 90 and 99 mmHg have been receiving medical treatment for hypertension for more than one year

Exclusion criteria:
Patients with a habit of physical activity or special diet such as yoga, meditation, auriculotherapy, acupuncture, etc. Taking more than one type of blood pressure medicine per day patients with high blood pressure secondary to other diseases receiving acupuncture treatment in the last month

Age
From **25 years** old to **50 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Care provider

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
Randomized

Randomization description
Simple randomization method: sealed envelopes and numbers 1 to 30 are written on each paper, and then each envelope is assigned to one person by lottery and numbers 1, 4, 7 and ... so on. belong to the first group and the numbers 2 5 8 and... to the second group and the numbers 3 6 9 and ... They belong to the third group

Blinding (investigator's opinion)
Single blinded

Blinding description
Only the person responsible for blood pressure measurement is unaware of the grouping of people

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Semnan University of Medical Sciences

Street address
Pasteur Square, Western Pastor St., Ajideh St., Gudarzi Alley, Kambiz Dead End, No. 2, Unit 2

City
Tehran

Province
Tehran

Postal code
1318845581

Approval date
2023-03-13, 1401/12/22

Ethics committee reference number
IR.SEMUMS.REC.1402.002

Health conditions studied

1

Description of health condition studied
high blood pressure

ICD-10 code
I10

ICD-10 code description
Essential (primary) hypertension

Primary outcomes

1

Description
Systolic and diastolic blood pressure

Timepoint
Before the intervention - before the first session - after the first session - at the end of 8 sessions - one month follow-up

Method of measurement
Digital blood pressure measuring device - 24-hour blood pressure holter device

2

Description
heart rate

Timepoint
Before the intervention - before the first session - after the first session - at the end of 8 sessions - one month follow-up

Method of measurement
Digital blood pressure measuring device - 24-hour blood pressure holter device

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Applying electroacupuncture in the form of 2 sessions a week for 4 weeks, each session will last 30 minutes, and during this period, 10 needles will be inserted in points LR3, ST36, PC6, PC5, and LI11, and electric current with a frequency of 2 Hz and an intensity of 2 mA will be established by SDZ II device.

Category
Rehabilitation

2

Description
Intervention group: Applying laser acupuncture in the form of 2 sessions a week for 4 weeks, each session will last 30 minutes, and during this time, the low-power laser will be placed on the LR3, ST36, PC6, PC5, and LI11 points. These points are bilaterally on the body, and the 500 milliwatt laser will be placed on each point for 3 minutes.

Category
Rehabilitation

3

Description
Control group: Taking medicines that are already taken by the patient and no change or intervention will happen.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Semnan University of Medical Sciences Research Center Clinic

Full name of responsible person
Majid Mohammadkhani

Street address
Mashahir Square towards Saadi Square, Research Center Clinic

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Semnan University of Medical Sciences

Full name of responsible person
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Street address
Kilometer 5, Damghan Road, University Educational Complex, first floor, west side of the main building

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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
Semnan 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
Semnan University of Medical Sciences

Full name of responsible person
Hamidreza Alibabaei

Position
Master's student in sports physiotherapy

Latest degree
Bachelor

Other areas of specialty/work
Physiotherapy

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
It will be published as an article
When the data will become available and for how long
It will be published as an article
To whom data/document is available
-
Under which criteria data/document could be used
-
From where data/document is obtainable
It will be published as an article
What processes are involved for a request to access data/document
It will be published as an article
Comments