Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Effect of Ear Acupuncture Using ASP needles in Improving Headache and Other Symptoms in comparison with Control Group (no therapeutic intervention) in Migraine Patients.

Protocol summary

Study aim

The purpose of this study isto investigate the effect of auricular acupuncture with semi-permanent ASP needles on migraine patients.

Design

A single blind randomized clinical trial with control group

Settings and conduct

80 patients with migraine headache regardless of its type (aura or no aura) were referred to acupuncture clinic of Ayatollah Kashani hospital in Isfahan, Iran. Patients were blinded to the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients with migraine between the ages of 18 and 65 years Exclusion criteria: Pregnant women, patients with severe coagulation problems, patients with advanced malignancy or underlying disease, non-migraine headaches, history of drug use or medication abuse or alcohol dependence, history of neurological or psychiatric illness, history of asthma or respiratory problems , Analgesic for chronic pain more than three days a month, previous auricular acupuncture history, prophylactic migraine medication use within last 6 months, severe ear abnormalities, head or facial neuralgia, aura without headache, Migraine headache onset after age 50

Intervention groups

Intervention group treated with auricular acupuncture ear acupuncture using semi-permanent ASP needles on active points of the ears and then a label was placed on each needle. In the control group only a label was placed on the inactive points of the ears.

Main outcome variables

Severity of headache, headache frequency, dose of Novafen, severity of nausea, vomiting frequency

General information

Reason for update

Changing the person responsible for the scientific accountability of the trial Correcting the job position and the person's latest degree responsible for the public accountability of the trial Correcting the job position and latest degree of person responsible for updating information

Acronym

IRCT registration information

IRCT registration number: **IRCT20200213046477N1**
Registration date: **2020-03-18, 1398/12/28**
Registration timing: **retrospective**

Last update: **2020-03-30, 1399/01/11**
Update count: **1**

Registration date

2020-03-18, 1398/12/28

Registrant information

Name

iman reisi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3223 9619

Email address

imanr20@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-22, 1397/09/01

Expected recruitment end date

2019-09-23, 1398/07/01

Actual recruitment start date
2018-12-08, 1397/09/17
Actual recruitment end date
2019-09-23, 1398/07/01
Trial completion date
2019-10-23, 1398/08/01

Scientific title
Effect of Ear Acupuncture Using ASP needles in Improving Headache and Other Symptoms in comparison with Control Group (no therapeutic intervention) in Migraine Patients.

Public title
Effects of Ear Acupuncture Using ASP Needles in Control of Migraine Symptoms
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients with migraine who need treatment The ages of 18 to 65 Consent to participate in the study
Exclusion criteria:
Pregnant women Patients with severe coagulation problems receiving anti-coagulant medications in which acupuncture may cause bleeding Patients with advanced malignancies or underlying diseases Patients with non-migraine headaches Patients with a history of drug or alcohol abuse or alcohol dependence A history of neurological or psychiatric illnesses Patients with asthma or respiratory problems Analgesic use for chronic pain more than three days a month Prior auricular acupuncture history Use of prophylactic migraine medication within the past six months Severe ear abnormalities Head or facial neuralgia Other neurological diseases Aura without headache Migraine headache incidence after age 50
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Participant

Sample size
Target sample size: **84**
Actual sample size reached: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Simple randomization using the toss method
Blinding (investigator's opinion)
Single blinded
Blinding description
In the control or sham group, In areas where the point-finding device detected to be inactive, a needle-free patch was inserted.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Hezar Jarib
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2018-12-08, 1397/09/17
Ethics committee reference number
Ir.mui.med.rec.1397.153

Health conditions studied

1

Description of health condition studied
Migraine
ICD-10 code
G43
ICD-10 code description
Migraine

Primary outcomes

1

Description
Headache
Timepoint
weekly for a month
Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
Nausea
Timepoint
Weekly for a month
Method of measurement
Visual Analogue Scale

Intervention groups

1

Description
Intervention group:In this group, Treatment wwas done using auricular acupuncture with semi-permanent ASP needles in the active ear pionts. After examining 15 migraine-affected acupuncture points by the Pointoselect pointers in each ear, active points were found and a maximum of 4 ASP needles were implanted in the most active points in each ear and then labled. The technique was repeated for patients after two weeks and patients were visited weekly for up to one month.

Category
Treatment - Devices

2

Description
Control group: In the control or sham group, a piece of needle-free adhesive was inserted at points identified by the Pointoselect pointers as inactive. The technique was repeated for patients after two weeks and patients were visited weekly for up to one month.

Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
Ayatollah Kashani Hospital

Full name of responsible person
Mehran Rezvani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Sponsor Vice chancellor for research, Isfahan University of Medical Sciences

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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
Sponsor Vice chancellor for research, Isfahan 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
Esfahan University of Medical Sciences

Full name of responsible person
Iman Raisi

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Anesthesiology

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Person responsible for scientific inquiries

Contact

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Esfahan University of Medical Sciences

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Specialist
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Person responsible for updating data

Contact
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be 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