Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Compare the effect of foot reflexology massage on headache intensity in patients receiving intravenous nitroglycerin in the intervention, placebo and control groups

Protocol summary

Summary

This study aimed to evaluate the impact of reflexology massage on headache caused by intravenous nitroglycerin in patients admitted to the hospital. This study is an experimental study (pre and post-test) will be conducted on patients receiving intravenous nitroglycerin in Seyyed-o-Shohada hospital of Urmia. Seventy five eligible patients will enter to study randomly, then allocate to the intervention (n=25), placebo (n=25) and control (n=25) groups, randomly. Inclusion criteria, including: being male, having a record in the mentioned hospital's wards and willing to participate in the study. Headache intensity will be measured in all three groups using the numerical pain scale. The intervention is reflexology massage. So, the upper part of the patient's toe, the spot of reflection related to head will be massaged for both legs in the intervention group at two steps for 20 minutes. An unspecified spot at the foot (heel) that is not linked to head will be massaged in the placebo group. The numerical pain scale will be used to evaluate the severity of headaches after the intervention. Reflexology massage is an independent variable and intravenous nitroglycerin induced headache is the dependent variable in this study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015042922010N1**
Registration date: **2016-02-12, 1394/11/23**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2016-02-12, 1394/11/23

Registrant information

Name

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Name of organization / entity

Urmia University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Governmental

Expected recruitment start date

2015-05-22, 1394/03/01

Expected recruitment end date

2015-10-22, 1394/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Compare the effect of foot reflexology massage on headache intensity in patients receiving intravenous nitroglycerin in the intervention, placebo and control groups

Public title

The effect of reflexology massage on headache caused by intravenous nitroglycerin

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: - Willing to participate in the study. - Not having cognitive or behavioral and vision disorders during the intervention that prevents using the numerical pain scale in the patients. - Not having orthopedic problems or wounds, injuries and burns on the legs, as well as diabetic foot ulcers. - Not having an advanced neurological disorder such as MS, Parkinson's disease, Guillain-Barre syndrome, progressive Myasthenia Gravis and diabetic neuropathy. - Not having a serious physical or mental illness to prevent intervention. - Not having a headache before the administration of nitroglycerin. - Not having an addiction to drugs, sedatives, alcohol, etc. - Not taking analgesics and nerve- muscle blockers shortly before the intervention. - Not having a long history of taking nitroglycerin. - Not having a history of using reflexology massage. Exclusion criteria: - Incidence of severe complications during the study. - Patient death. - Dissatisfaction of attending physician. - Losing of the patient's consciousness.

Age

From **18 years** old to **90 years** old

Gender

Male

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size:

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Urmia University of Medical Sciences

Street address

End of Emergency Alley, Resalat Boulevard, Urmia

City

urmia

Postal code

5714783734

Approval date

2015-04-29, 1394/02/09

Ethics committee reference number

umsu.rec.1394.28

Health conditions studied

1

Description of health condition studied

Drug-induced headache

ICD-10 code

G44.4

ICD-10 code description

Drug-induced headache, not elsewhere classified

Primary outcomes

1

Description

headache

Timepoint

Before and immediately after the intervention

Method of measurement

Numerical Pain Scale

Secondary outcomes

empty

Intervention groups

1

Description

The patient's feet are cleaned using a wet towel. After cleaning the feet, the reflexology massage is given based on Ingham method. To do this, the patient's heel is held by left hand and foot is bent from the ankle. Then, upper part of the patient's toe, which is linked to the reflection spot of the head will be massaged. This procedure is performed for both legs for 20 minutes (10 minutes for each leg separately).

Category

Other

2

Description

In the placebo group an unspecified point in the foot (heel) that is not related to head, will be massaged.

Category

Placebo

3

Description

No action will be taken in the control group.

Category

Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Seyyed Al-Shohada Hospital of Urmia
Full name of responsible person
Street address
In front of Samadzadeh Street, Shahrivar 17th Boulevard, Vali asr Boulevard
City
Urmia

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Urmia University of Medical Sciences
Full name of responsible person
Iraj Mohebbi
Street address
End of Emergency Alley, Resalat Boulevard, Urmia
City
Urmia
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Urmia University of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Urmia University of Medical Sciences
Full name of responsible person
Shams Aldin Shams
Position
Master / Trainer
Other areas of specialty/work
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Person responsible for scientific inquiries

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Fax
Email
nima.imany@yahoo.com
Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty