Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparing the effect of foot reflexology and acupressure on treatment of headache in patient receiving Nitroglycerin infusion in female patients admitted to cardiac emergency department

Protocol summary

Summary

Comparing the effect of foot reflexology with acupressure on treatment of headache in patient receiving Nitroglycerine infusion in female patients admitted to cardiac emergency department. This study is clinical trial study will be conducted in treatment of headache on patients receiving Nitroglycerine infusion in Martyr Rajaei Hospital of karaj. Ninety nine eligible female patients will enter to study randomly, then allocate to the foot reflexology (n=33), acupressure (n=33) and placebo (n=33) groups, randomly. Ninety nine patients receiving Nitroglycerine infusion will be selected with available sampling method and then using permuted block randomization allocated in three groups foot reflexology (n=33), acupressure (n=33) and placebo (n=33). Intensity and quality of headache, and also vital sign will be measured in all three groups. The intervention is reflexology massage, 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. The intervention is acupressure, 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. In intervention group acupressore will be done in hegu point for 2 minutes and rest for 2 minutes and this procidure was repeated for 10 minutes. At 15 minutes after the first intervention, the second intervention will be repeated for 10 minutes. Touch will perform that is not linked to head will be massaged in the placebo group.. Intensity and quality of headache intensity will be used after the first intervention and after second intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201711107529N16**
Registration date: **2017-11-20, 1396/08/29**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-11-20, 1396/08/29

Registrant information

Name
Nahid Rejeh
Name of organization / entity
Shahed University
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Recruitment status

Recruitment complete

Funding source

Shahed University Vice chancellor for research

Expected recruitment start date

2017-11-22, 1396/09/01

Expected recruitment end date

2018-05-22, 1397/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of foot reflexology and acupressure on treatment of headache in patient receiving Nitroglycerin infusion in female patients admitted to cardiac emergency department

Public title

Comparing the effect of foot reflexology and acupressure on treatment of headache in patient receiving Nitroglycerin infusion

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: willing to participate in the study; age between 18 to 65; The absence of verbal and visual disorders; The absence of sensory-motor disorders; The absence of advanced neurological disorders; The absence of clotting problems, peripheral vascular disease, peripheral neuropathy and DVT limb; The absence of diagnosed psychiatric disorder; The absence of a headache before the administration of Nitroglycerine; the absence of any history of headache in patients; not having an addiction to drugs, sedatives, alcohol; Not using analgesics and nerve- muscle blockers 4 hours before the intervention; not having a long history of taking Nitroglycerine; The absence of history of using reflexology or acupressure; Not using of steroidal and non-steroidal anti-inflammatory drugs, anticoagulation, chemotherapy. Exclusion criteria: Incidence of severe complications during the study; Pain in other parts of the body other than the head; the severity of the pain so that the patient can not tolerate; Use analgesics drugs during the study; Dissatisfaction of attending physician or patient.

Age

From **18 years** old to **65 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **99**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Eligible patients will be selected through convenience sampling and will be randomly assigned into 2 groups using permuted block randomization with allocation ratio of 1: 1: 1. Random allocation sequence will be determined using a computerized program. Opaque sealed sequentially numbered envelopes from number 1 to 99 will be used for allocation concealment.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shahed University

Street address

Shahed University, Opposite to Holy Shrine of Imam Khomeini, Tehran-Qom Freeway, Tehran.

City

Tehran

Postal code

Approval date

2017-11-06, 1396/08/15

Ethics committee reference number

Shahed.REC.1396.50

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

Intensity of headache

Timepoint

Before the intervention , after the first intervention and after second intervention

Method of measurement

Visual Analog Pain Scale

2

Description

Quality of headache

Timepoint

Before the intervention, after the first intervention and after second intervention

Method of measurement

McGill Pain Questionnaire

Secondary outcomes

1

Description

Heart rate

Timepoint

Before the intervention, after the first intervention and after second intervention

Method of measurement

Monitoring system

2

Description

Systolic Blood pressure

Timepoint

Before the intervention, after the first intervention and after second intervention

Method of measurement

Monitoring system

3

Description

Diastolic blood pressure

Timepoint

Before the intervention, after the first intervention and after second intervention

Method of measurement

Monitoring system

4

Description

Mean blood pressure

Timepoint

Before the intervention, after the first intervention and after second intervention

Method of measurement

Monitoring system

5

Description

Respiratory rate

Timepoint

Before the intervention, after the first intervention and after second intervention

Method of measurement

Monitoring system

6

Description

Oxygen saturation of arterial blood

Timepoint

Before the intervention, after the first intervention and after second intervention

Method of measurement

pulse oximeter

Intervention groups

1

Description

The intervention is reflexology massage, 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. The intervention is acupressure, 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.

Category

Treatment - Other

2

Description

In intervention group acupressore will be done in hegu point for 2 minutes and rest for 2 minutes and this procidure was repeated for 10 minutes. At 15 minutes after the first intervention, the second intervention will be repeated for 10 minutes.

Category

Treatment - Other

3

Description

Touch will perform that is not linked to head will be massaged in the placebo group.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Martyr Rajaei Hospital

Full name of responsible person

Maryam Fatahi

Street address

City

karaj

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed University Vice Chancellor For Research

Full name of responsible person

Dr. Zahra Kiasalari

Street address

Shahed University, Opposite to Holy Shrine Of Imam Khomeini, Tehran-Qom Express Way, Tehran.

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahed University Vice Chancellor For Research

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

Shahed University

Full name of responsible person

Dr. Nahid Rejeh

Position

Associate Professor

Other areas of specialty/work

Street address

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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