

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The Effect of Foot Reflexology Massage on Physiological Indices in Stroke Patients

Protocol summary

Study aim

The Effect of Foot Reflexology Massage on Physiological Indices in Stroke Patients

Design

A clinical trial with a control group, one-blind, randomized on 60 patients

Settings and conduct

This study was performed on patients with stroke in the neurology department of Ali Ibn Abi Taleb Hospital in Rafsanjan.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Diagnosis of stroke; GCS over 7; age over 30 years; heart rate greater than 60 beats per minute; temperature greater than 36.5 °C and systolic blood pressure higher than 90. Non inclusion criteria: Arrhythmia; taking nitroglycerin-dopamine and Dobutamine drugs; have a history of drug abuse (addiction); not tolerating the intervention and having a history of mental illness.

Intervention groups

In the Intervention group, the researcher carries a reflective massage for 30 minutes (15 minutes for each foot). In this method, reflection points of soles (solar network and the pituitary related points) are pressed using the index and thumbs fingers. Control group receive simple massage on the foot.

Main outcome variables

Blood pressure; heart rate; temperature; respiration; percentage of arterial oxygen saturation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180304038936N3**

Registration date: **2018-09-04, 1397/06/13**

Registration timing: **registered_while_recruiting**

Last update: **2018-09-04, 1397/06/13**

Update count: **0**

Registration date

2018-09-04, 1397/06/13

Registrant information

Name

Ahmadreza Sayadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3425 5900

Email address

a.sayadi@rums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-23, 1397/02/03

Expected recruitment end date

2019-04-23, 1398/02/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Foot Reflexology Massage on Physiological Indices in Stroke Patients

Public title

The Effect of foot reflexology massage on physiological indices

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Definite diagnosis of stroke level of consciousness (GCS)
over 7 Age over 30 years Heart rate greater than 60
beats per minute Temperature greater than 36.5 ° C
Systolic blood pressure higher than 90

Exclusion criteria:

Patients with arrhythmia Patients who are taking
nitroglycerin-dopamine and Duobutamin drugs Have a
history of drug use Do not tolerate intervention Have a
history of mental illness Have acute conditions during the
intervention

Age

From **30 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Stratified randomization by minimization method based
on age and blood pressure variables.

Blinding (investigator's opinion)

Single blinded

Blinding description

Participants do not know which group is being
investigated as intervention group

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Rafsanjan University of Medical
Sciences

Street address

Rafsanjan

City

Rafsanjan

Province

Kerman

Postal code

7717933777

Approval date

2018-04-17, 1397/01/28

Ethics committee reference number

IR.RUMS.REC.1397.020

Health conditions studied

1

Description of health condition studied

stroke

ICD-10 code

I64

ICD-10 code description

Stroke, not specified as haemorrhage or infarction

Primary outcomes

1

Description

Mean of blood pressure

Timepoint

10 minutes before intervention, immediately after
intervention, 10 minutes after intervention and 30
minutes after intervention

Method of measurement

Alpk2 sphygmomanometer

2

Description

Number of respiration per minute

Timepoint

10 minutes before intervention, immediately after
intervention, 10 minutes after intervention and 30
minutes after intervention

Method of measurement

Counting number of breaths

3

Description

Mean of temperature

Timepoint

10 minutes before intervention, immediately after
intervention, 10 minutes after intervention and 30
minutes after intervention

Method of measurement

Easylife digital thermometer

4

Description

Number of heart rate per minute

Timepoint

10 minutes before intervention, immediately after
intervention, 10 minutes after intervention and 30
minutes after intervention

Method of measurement

PC-66B pulse oximeter device

5

Description

Percentage of oxygen saturation of arterial blood

Timepoint

10 minutes before intervention, immediately after

intervention, 10 minutes after intervention and 30 minutes after intervention
Method of measurement
PC-66B pulse oximeter device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This group receive reflexology massage for 30 minutes (15 minutes for each foot) on the second day of hospitalization. In this method, reflection points of soles (solar network and the pituitary-related points) are pressed using the index finger and thumbs.

Category

Other

2

Description

Control group: This group receive simple massage for 30 minutes (15 minutes for each foot) on the second day of hospitalization.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ali Ibn Abi Taleb Hospital

Full name of responsible person

Azam Talebi

Street address

Parastar Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rafsanjan University of Medical Sciences

Full name of responsible person

Ali Shamsizadeh

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Imam Ali Blvd

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vcrt@rums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Rafsanjan 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

Rafsanjan University of Medical Sciences

Full name of responsible person

Ahmad Reza Sayadi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Psychology

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Person responsible for updating data

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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

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable