

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

01 Jul 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

**City**

Rafsanjan

**Province**

Kerman

**Postal code**

7718796755

**Phone**

+98 34 3425 5900

**Email**

a.talebi307@gmail.com

**Sponsors / Funding sources**

**1**

**Sponsor**

**Name of organization / entity**

Rafsanjan University of Medical Sciences

**Full name of responsible person**

Ali Shamsizadeh

**Street address**

Imam Ali Blvd

**City**

Rafsanjan

**Province**

Kerman

**Postal code**

7717933777

**Phone**

+98 34 3428 0097

**Email**

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 scientific inquiries**

**Contact**

**Name of organization / entity**

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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

**Person responsible for updating data****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.