

Clinical Trial Protocol

Iranian Registry of Clinical Trials

24 Jun 2026

The effect of foot bath on physiological parameters and anxiety levels in patients with acute stroke hospitalized in the neurology Ward of Towhid hospital in Sanandaj, 2018

Protocol summary

Study aim

Effect of foot bath on physiological indexes and anxiety levels in patients with acute stroke

Design

In this study, 60 patients were randomly divided into two groups intervention (n = 30) and controls (n = 30) using sealed envelopes.

Settings and conduct

After obtaining the necessary permission, a study is conducted on patients with stroke admitted to the neurology department of Tohid Hospital in Sanandaj. Following the explanation of the research and obtaining written consent from them and ensuring the confidentiality of their information, they are selected as samples. The study is one-sided, and the data will be analyzed without informing the advisors of the type of groups.

Participants/Inclusion and exclusion criteria

Being patient alert, Age >30, Being healthy at least one of the lower extremities of sensation and movement, Diagnosis of stroke by physician, The absence of acute and severe hemodynamic disorders, Not having a history of drug use, Lack of skin disorders in the lower extremities, Non-deformity in the lower limbs, Lack of abnormal blood supply and oxygenation to the lower extremities, Lack of musculoskeletal disorders in the lower extremity

Intervention groups

In the test group, the patient is first seated for 10 minutes at the edge of the bed, and immediately for 15 minutes, the foot bath is done using a foot bath in a sitting position on the bed edge, and then the legs of the patient will be dried with a disposable towel. Patients in the control group do not receive any interventions and sit only on the edge of the bed for only 10 minutes.

Main outcome variables

Temperatures blood pressure heart beat Respiratory rate

Percentage of arterial oxygen saturation Anxiety

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180411039274N1**

Registration date: **2018-08-02, 1397/05/11**

Registration timing: **registered_while_recruiting**

Last update: **2018-08-02, 1397/05/11**

Update count: **0**

Registration date

2018-08-02, 1397/05/11

Registrant information

Name

Fazel Dehvan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 87 3324 6141

Email address

dehvan.f@muk.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-07-23, 1397/05/01

Expected recruitment end date

2018-10-23, 1397/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of foot bath on physiological parameters and anxiety levels in patients with acute stroke hospitalized in the neurology Ward of Towhid hospital in Sanandaj, 2018

Public title

The effect of foot bath on physiological parameters and anxiety levels in patients with acute stroke

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Being patient alert, Age >30, Being healthy at least one of the lower extremities of sensation and movement, Diagnosis of stroke by physician, The absence of acute and severe hemodynamic disorders, Not having a history of drug use, Lack of skin disorders in the lower extremities, Non-deformity in the lower limbs, Lack of abnormal blood supply and oxygenation to the lower extremities, Lack of musculoskeletal disorders in the lower extremity

Exclusion criteria:**Age**

From 30 years old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Using the method of Flip the coin and according to the size of the sample, the Flip the coin are repeated

Blinding (investigator's opinion)

Single blinded

Blinding description

Assigning proprietary code to questionnaires and the questionnaire will be provided to the statistics consultant for analysis without specifying the name of the group

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Kurdistan University of Medical Sciences

Street address

Pasdaran Street, Kurdistan University of Medical Sciences, Sanandaj city

City

Sanandaj

Province

Kurdistan

Postal code

66177-13446

Approval date

2018-06-11, 1397/03/21

Ethics committee reference number

IR.MUK.REC.1397/58

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**

Anxiety

Timepoint

Before and after intervention in each of the groups

Method of measurement

Anxiety Measurement Using Spielberger Standard Questionnaire

2**Description**

blood pressure

Timepoint

Before intervention And immediately, 15 minutes later and half an hour after the end of the intervention

Method of measurement

Using the Digital Pressure Gauge, Buerer Mark, Made in Germany

3**Description**

Temperatures

Timepoint

Before intervention And immediately, 15 minutes later and half an hour after the end of the intervention

Method of measurement

Using a tympanic digital thermometer

4

Description

Heart Rate

Timepoint

Before intervention And immediately, 15 minutes later and half an hour after the end of the intervention

Method of measurement

Using the touch of the apex area

5

Description

Respiratory Rate

Timepoint

Before intervention And immediately, 15 minutes later and half an hour after the end of the intervention

Method of measurement

By observing the movements of the chest in a minute

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In order to intervene in the test group, the patient is first placed on the edge of the bed for 10 minutes and will be done for 15 minutes using the foot bath (FB25- Beurer Made in Germany) in the sitting position on the bed edge (chair).And then the patient's legs are dried with disposable towel. During this period, the investigator will not talk with the patient to influence the patient's anxiety.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Tohid Hospital in Sanandaj

Full name of responsible person

Fazel Dehvan

Street address

Pasdaran St., Kurdistan University of Medical Sciences, Faculty of Nursing and Midwifery, Sanandaj City

City

Sanandaj

Province

Kurdistan

Postal code

66177-13446

Phone

+98 87 3366 4645

Email

dehvan.f@muk.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

Fazel Dehvan

Street address

Pasdaran St., Kurdistan University of Medical Sciences, Faculty of Nursing and Midwifery

City

Sanandaj

Province

Kurdistan

Postal code

66177-13446

Phone

+98 87 3366 4645

Email

dehvan.f@muk.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Sanandaj 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

Sanandaj University of Medical Sciences

Full name of responsible person

Fazel Dehvan

Position

Faculty member

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Pasdaran St., Kurdistan University of Medical Sciences, Faculty of Nursing and Midwifery

City

sanandaj

Province

Kurdistan

Postal code

66177-13446

Phone

+98 87 3366 4645

Email

dehvan.f@muk.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

fazel dehvan

Position

Faculty member

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Pasdaran St., Kurdistan University of Medical Sciences, Faculty of Nursing and Midwifery

City

sanandaj

Province

Kurdistan

Postal code

66177-13446

Phone

+98 87 3366 4645

Email

dehvan.f@muk.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Sanandaj University of Medical Sciences

Full name of responsible person

fazel dehvan

Position

Faculty member

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Pasdaran St., Kurdistan University of Medical Sciences, Faculty of Nursing and Midwifery

City

sanandaj

Province

Kurdistan

Postal code

66177-13446

Phone

+98 87 3366 4645

Email

dehvan.f@muk.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All individual participant data is shared after being unidentified

When the data will become available and for how long

Start the access period 7 months after publishing the results

To whom data/document is available

Data is only available for academic scholarly researchers

Under which criteria data/document could be used

There are no special conditions

From where data/document is obtainable

fazel dehvan - dehvan.f@muk.ac.ir - 00988733664645

What processes are involved for a request to access data/document

Sending a request to my email (dehvan.f@muk.ac.ir) will be answered after 10 - 15 days

Comments