

# 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

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##### Province

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#### 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

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sanandaj

##### Province

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**Person responsible for scientific inquiries**

**Contact**

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Sanandaj University of Medical Sciences

**Full name of responsible person**

fazel dehvan

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**Contact**

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**Email**

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**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**