

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

04 Oct 2023

### The effectiveness and non-effectiveness of adding electrical stimulation through the skin to stretching exercises on the changes in ankle range of motion in patients hospitalized in intensive care units

#### Protocol summary

##### Summary

This study will be done with aim to investigate the effectiveness of adding electrical stimulation through the skin to stretching exercises on the changes in ankle range of motion in patients hospitalized in intensive care units. This study is a single blind clinical trial. The study population will included all patients admitted to intensive care of hospitals in Kermanshah city. 36 patients will be selected in available method and in random permuted blocks will be assigned in two control and experimental groups. Before the intervention, the ankle dorsiflexion using standard goniometer will be measured. In the intervention group TENS current with stretching exercises is applied for 30 minutes at ankle. In the control group stretching exercises at the ankle are performed. In both groups stretching exercises are performed three times a week and each time 10 minutes for 2 weeks. After the intervention ankle dorsiflexion using a standard goniometer will be measured and difference between the two groups will be compared. Inclusion criteria: Patients who passes up to one week of admission in ICU; Aged 18 to 60 years; Patients who are unable to move their feet; Lack of musculoskeletal diseases and injuries in and around the ankle; ; Do not use electrical stimulation in the ankle in the past. Exclusion criteria: To cause skin allergy caused by contact electrodes during interventions; TENS intolerance during interventions

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2017010814333N64**  
Registration date: **2017-01-20, 1395/11/01**  
Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2017-01-20, 1395/11/01

##### Registrant information

###### Name

Feizollah Foroughi

###### Name of organization / entity

kermanshah University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 83 1821 4653

###### Email address

fforoughi@kums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research, Kermanshah University of Medical Sciences

##### Expected recruitment start date

2017-01-20, 1395/11/01

##### Expected recruitment end date

2017-02-19, 1395/12/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The effectiveness and non-effectiveness of adding electrical stimulation through the skin to stretching exercises on the changes in ankle range of motion in patients hospitalized in intensive care units

**Public title**

effectiveness of adding electrical stimulation through the skin to stretching exercises on the changes in ankle range of motion in patients hospitalized in intensive care units

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: Patients who passes up to one week of admission in ICU; Aged 18 to 60 years; Patients who are unable to move their feet; Lack of musculoskeletal diseases and injuries in and around the ankle; ; Do not use electrical stimulation in the ankle in the past. Exclusion criteria: To cause skin allergy caused by contact electrodes during interventions; TENS intolerance during interventions; The ability to move legs voluntarily during interventions

**Age**

From **18 years** old to **60 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **36**

**Randomization (investigator's opinion)**

Randomized

**Randomization description****Blinding (investigator's opinion)**

Single blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features**

Block randomization based on permutation

**Secondary Ids**

empty

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

Ethics committee of Kermanshah University of Medical Sciences

**Street address**

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

**City**

Kermanshah

**Postal code****Approval date**

2016-12-28, 1395/10/08

**Ethics committee reference number**

kums.rec.1395.563

**Health conditions studied****1****Description of health condition studied**

Stroke

**ICD-10 code**

I63.9

**ICD-10 code description**

Cerebral infarction, unspecified

**Primary outcomes****1****Description**

The ankle dorsiflexion

**Timepoint**

Baseline, the end of the study

**Method of measurement**

Using standard goniometer

**Secondary outcomes**

empty

**Intervention groups****1****Description**

In the intervention group TENS current with stretching exercises is applied at ankle

**Category**

Behavior

**2****Description**

In the control group stretching exercises at the ankle are performed

**Category**

Other

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Hospitals in Kermanshah

**Full name of responsible person**

Asghar Rostami

**Street address**

Emam Reza Hospital, Parastar Boulevard

**City**

Kermanshah

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice chancellor for research, Kermanshah University of Medical Sciences

**Full name of responsible person**

Koroush Hamzehee

**Street address**

Building No.2, Shahid Beheshti, Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences

**City**

Kermanshah

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice chancellor for research, Kermanshah University of Medical Sciences

**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**

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Dr. Ali akbar Visi Raygan

**Position**

Ph.D of Nursing

**Other areas of specialty/work****Street address**

School of Nursing & Midwifery, Dolatabad Boulevard, Eisar Square

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+98 83 3828 2101

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visi\_akbar@yahoo.com

**Web page address**

## Person responsible for updating data

**Contact****Name of organization / entity**

Kermanshah University of Medical Sciences

**Full name of responsible person**

Asghar Rostami

**Position**

Critical Care Nursing Graduate Student

**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*