

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

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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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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

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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