

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

The effect of the vibration on the level of consciousness in head trauma patients

Protocol summary

Study aim

The effect of the vibration on the level of consciousness in head trauma patients

Design

In a clinical trial, 50 head injured patients were selected through convenience sampling and were randomly assigned to intervention and control groups

Settings and conduct

50 head trauma patients were hospitalized in the ICU of Shahid Rajaee Hospital in Qazvin through the available sampling method and randomly divided into 2 groups

Participants/Inclusion and exclusion criteria

Inclusion criteria: All patients with head trauma in the intensive care unit: patients with head trauma have a level of consciousness of 5 - 12 • Age 15 - 65 years • Patients who have had at least 72 hours of injury and SIMV ventilator mod .Exclusion criteria: * The presence of fractures, ulcers, infections and skin disease in the wrist to the ends of both toes. Limitation on the movement of the lower limbs * amputation * Patients affected by a series of cases that have history, history of diabetes, coma in the past, sensory and neurological disorders, death

Intervention groups

In the control group, routine care was performed in all centers and in the intervention group, during the 7-day period, one day for 15 minutes, using a foot massage jacuzzi massage device, the leg shake was performed. Then, immediately before the intervention, one hour and three hours after skin irritation, the level of consciousness was assessed based on Glasgow's scale and vital signs. In the control group, the level of consciousness and vital signs parallel to the intervention group was evaluated.

Main outcome variables

vital sign, vibration, level of consciousness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180731040658N2**

Registration date: **2018-10-15, 1397/07/23**

Registration timing: **retrospective**

Last update: **2018-10-15, 1397/07/23**

Update count: **0**

Registration date

2018-10-15, 1397/07/23

Registrant information

Name

Fateme Nazifi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3368 5170

Email address

f.nazifi@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-05-22, 1396/03/01

Expected recruitment end date

2017-12-21, 1396/09/30

Actual recruitment start date

2017-05-22, 1396/03/01

Actual recruitment end date

2017-12-21, 1396/09/30

Trial completion date

2017-12-21, 1396/09/30

Scientific title

The effect of the vibration on the level of consciousness in head trauma patients

Public title

The effect of the vibration on the level of consciousness in head trauma patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

patients with head trauma with a level of consciousness of 5 - 12 age of 17-65 years patients who at least 72 hours have passed since their injury SIMV mod For patients connected to the ventilator

Exclusion criteria:

head trauma patients who based on records and history have a history of the diabetes, a history of coma in the past and a history of sensory and neurological disorders fracture, ulcer, infection and skin disease in the wrist to the extremities of both feet fingers, limitation of movement of the lower limbs lower limb amputation Patients receiving infusion of sedation medication can not be stopped death

Age

From **17 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Actual sample size reached: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple random sampling At first, the random allocation of samples was done for two groups of control and intervention using a two-ball orbital draw, so that the white ball indicates the control group and the red ball indicates the intervention group.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Qazvin University of Medical

Sciences

Street address

Qazvin University of Medical Sciences, Bahonar Blvd

City

Qazvin

Province

Qazvin

Postal code

3419915315

Approval date

2017-04-15, 1396/01/26

Ethics committee reference number

IR.QUMS.REC.1396.26

Health conditions studied

1

Description of health condition studied

Head trauma patients

ICD-10 code

S00.90XA

ICD-10 code description

Unspecified superficial injury of unspecified part of head, initial encounter

Primary outcomes

1

Description

level of consciousness

Timepoint

Control the level of consciousness before, one and three hours after the intervention with vibration

Method of measurement

GCS Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Performing vibration with 50 Hz Frequency of legs from fingers to ankles using a jacuzzi massager machine Made in China once a day for 15 minutes after an appointment and for 7 consecutive days

Category

Rehabilitation

2

Description

Control group: Control group: In the control group, the usual care was taken in all centers. In the control group, the level of consciousness and vital signs parallel to the intervention group was evaluated and recorded

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rajaee hospital in Qazvin

Full name of responsible person

Fateme Nazifi

Street address

Shahid Rajaee hospital, North Padegan Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr.Amir Peimani

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Grant name

Grant code / Reference number

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

No

Title of funding source

Qazvin 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

Person responsible for general inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Fateme Nazifi

Position

Nurse, student

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for updating data

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable