

# 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

**City**

Qazvin

**Province**

Qazvin

**Postal code**

3413996134

**Phone**

+98 28 3333 5800

**Email**

hosrajaee@qums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Dr.Amir Peimani

**Street address**

Qazvin University of Medical Sciences, Bahonar Blvd

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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

**Street address**

No. 92, Alley 33, Shahid Babaei Street

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## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

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**Position**

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Master

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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