

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of warm baths with and without vibration on level of consciousness in patients with head trauma who admitted to the intensive care unit

#### Protocol summary

##### Study aim

comparison of the effect of warm bath with and without vibration on the level of consciousness of head trauma patients in Shahid Rajaei Hospital of Qazvin

##### Design

A clinical trial, 100 head trauma, control group with parallel groups were selected by convenience sampling and were randomly assigned to intervention and control groups

##### Settings and conduct

100 head trauma patients were hospitalized in the ICU of Shahid Rajaei Hospital in Qazvin through the available sampling method and randomly divided into 4 groups

##### Participants/Inclusion and exclusion criteria

Entry 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  
Exit 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

##### Intervention groups

In the control group, routine care was performed, and in the intervention group, for 7 days, once a day for 15 minutes, using a jacuzzi massage device. The first method was a warm foot without vibration And pouring water at a temperature of  $\pm 40^{\circ}\text{C}$  was carried out inside the machine. In the second method, the foot warm bath was performed at a frequency of 50 Hz. In the third method, only shaking feet without hot water was used. 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

warm footbath, vital sign, vibration, level of consciousness

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180731040658N1**

Registration date: **2018-08-19, 1397/05/28**

Registration timing: **retrospective**

Last update: **2018-08-19, 1397/05/28**

Update count: **0**

##### Registration date

2018-08-19, 1397/05/28

##### 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**

empty

**Scientific title**

Comparison of warm baths with and without vibration on level of consciousness in patients with head trauma who admitted to the intensive care unit

**Public title**

Investigating the effect of warm bath and vibration on the level of consciousness of patients with head trauma

**Purpose**

Supportive

**Inclusion/Exclusion criteria****Inclusion criteria:**

Patients with head trauma, based on the GCS, a level of consciousness of between 5 and 12 Patients with head trauma range from 15 to 65 years Patients with head trauma, which was 72 hours past their injury

**Exclusion criteria:**

The presence of fractures, ulcers, infections and skin disease in the wrist to the extremities of both fingers, limitation of movement of the lower limbs Lower limb amputees Patients who have a history of coma in the past have a sensory and neurological disorder, based on history records and history of diabetes

**Age**

From **15 years** old to **65 years** old

**Gender**

Both

**Phase**

N/A

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **100**

Actual sample size reached: **100**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

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. After placing the specimen in the intervention group, a draw of three blue, green and yellow balls was used in the intervention group, so that the blue ball indicates the intervention of warm water, the green ball indicates the intervention of warm water and vibration and the yellow arrow indicates vibration

**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**

Change in consciousness level based on GCS

**Timepoint**

Measurement of consciousness level of samples immediately before intervention, 1 and 3 hours after intervention with warm water and vibration and also its measurement in the control group

**Method of measurement**

Use Glasgow Coma Scale

**Secondary outcomes**

empty

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

In the intervention group, the patients were eligible for 7 days, once a day, 18 to 16 hours, using a jacuzzi

massage device in China for a period of 15 minutes, making the Chinese bath warm feet with and without vibration from the wrists to the femurs of skin irritation. Intervention group: First intervention: The warm bath was carried out without vibration and pouring of water at a temperature of  $2 \pm 40$  ° C. The second step was a warm foot bath with 50 Hz oscillation of the frequency using a Jacuzzi massager. Third intervention: Only the vibration of the feet without warm water was used.

**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**

Other

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

Shahid Rajaei hospital in Qazvin

**Full name of responsible person**

Fateme Nazifi

**Street address**

Shahid Rajaei 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

**City**

Qazvin

**Province**

Qazvin

**Postal code**

3419915315

**Phone**

+98 28 3333 8034

**Email**

f.nazifi@qums.ac.ir

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

Yes

**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**

Academic

**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**

Bachelor

**Other areas of specialty/work**

Nursery

**Street address**

No. 92, Alley 33, Shahid Babaei Street

**City**

Qazvin

**Province**

Qazvin

**Postal code**

3414678113

**Phone**

+98 28 3368 5170

**Fax****Email**

f.nazifi@qums.ac.ir

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

Fateme Nazifi

**Position**

Nurse, student

**Latest degree**

Bachelor

**Other areas of specialty/work**

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**Fax**  
**Email**  
f.nazifi@qums.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**  
Qazvin University of Medical Sciences  
**Full name of responsible person**  
Fateme Nazifi  
**Position**  
Nurse, student  
**Latest degree**  
Bachelor  
**Other areas of specialty/work**  
Nursery  
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**Email**  
f.nazifi@qums.ac.ir

## 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

Undecided - It is not yet known if there will be a plan to make this available

### Statistical Analysis Plan

No - There is not a plan to make this available

### Informed Consent Form

No - There is not a plan to make this available

### Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

### Analytic Code

No - There is not a plan to make this available

### Data Dictionary

No - There is not a plan to make this available