

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Comparing of the effect of foot reflexive massage and tactile stimulation on consciousness levels and physiological indices of traumatic brain injury patients admitted to Intensive care unit

Protocol summary

Study aim

Comparing of the effect of foot reflexive massage and tactile stimulation on consciousness levels and physiological indices of traumatic brain injury patients

Design

This study is a clinical trial. The study population included all traumatic brain injury patients in the ICU. 60 eligible patients selected conveniently and randomly assigned to four groups (three intervention and one control group)

Settings and conduct

This study, carried out at selected Hospital in Qazvin city for two weeks, twice a day, 11:00 am & 15:00 pm. before and after intervention, the level of consciousness, vital signs, and arterial oxygen saturation in all for groups recorded in a checklist.

Participants/Inclusion and exclusion criteria

Patients is hospitalized with head trauma (Types of brain hematomas and diffuse axon damage). The patient has pupil reflexes at the entrance to the ICU section. The patient already has no history of GCS fluctuations within a few days prior to the trauma. The patient already has no history of Diabet.

Intervention groups

First intervention group 20 minutes feet massage daily, second intervention group 20 minutes hand touch daily, third intervention group 20 minutes feet massage and 20 minutes hand touch daily were done, forth group (control group) not received any intervention.

Main outcome variables

feet massage, hand touch, blood pressure, level of consciousness

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180726040604N1**

Registration date: **2018-09-22, 1397/06/31**

Registration timing: **retrospective**

Last update: **2018-09-22, 1397/06/31**

Update count: **0**

Registration date

2018-09-22, 1397/06/31

Registrant information

Name

Bagheiatallah Salehi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 28 3332 3236

Email address

icusalehi@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-03-21, 1397/01/01

Actual recruitment start date

2017-12-22, 1396/10/01

Actual recruitment end date

2018-03-21, 1397/01/01

Trial completion date

2018-03-21, 1397/01/01

Scientific title

Comparing of the effect of foot reflexive massage and tactile stimulation on consciousness levels and physiological indices of traumatic brain injury patients

admitted to Intensive care unit

Public title

The effect of foot reflexive massage and tactile stimulation on consciousness levels and physiological indices of traumatic brain injury patients admitted to Intensive care unit

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients is hospitalized with head trauma (Types of brain hematomas and diffuse axon damage). The patient has pupil reflexes at the entrance to the ICU section. The patient already has no history of mental illness, GCS fluctuations within a few days prior to the trauma. The patient already has no history of Diabet.

Exclusion criteria:

History of Diabet History of Coma Narcotic addiction

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: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

The sampling method is block randomization and patients are classified into four groups by block random allocation method.

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, Qazvin

City

Qazvin

Province

Qazvin

Postal code

34197-59811

Approval date

2017-12-27, 1396/10/06

Ethics committee reference number

IR.QUMS.REC.1396.346

Health conditions studied

1

Description of health condition studied

Brain injury

ICD-10 code

T06

ICD-10 code description

Injuries of brain and cranial nerves with injuries of nerves and spinal cord at neck level

Primary outcomes

1

Description

The level of consciousness, vital signs, and arterial oxygen saturation

Timepoint

Everyday before and after intervention

Method of measurement

Glasco Coma Scale

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group will receive 10 minutes wrists and palms hand touch twice a day ,11:00 am and 15:00 pm , for two weeks

Category

Rehabilitation

2

Description

The second intervention group will receive 10 minutes feet massage from the wrist to the fingers,twice a day,11:00 am and 15:00 pm, for two weeks.

Category

Rehabilitation

3

Description

The Third intervention group will receive 10 minutes wrists and palms hand touch and 10 minutes feet

massage from the wrist to the fingers, twice a day, 11:00 am and 15:00 pm, for two weeks.

Category

Rehabilitation

4

Description

The control group will not receive any sensory stimulation.

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Rajae Hospital

Full name of responsible person

علی طارمها

Street address

No. 1, Padegan Ave

City

Qazvin

Province

Qazvin

Postal code

3413996134

Phone

+98 28 3333 5800

Email

hosrajaee@qums.ac.ir

Web page address

http://hosrajaee.qums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Manochehr Mahram

Street address

Bahonar Blvd.,

City

Qazvin

Province

Qazvin

Postal code

3419759811

Phone

+98 28 3337 5518

Fax

+98 28 3337 7089

Email

chancellor@qums.ac.ir

Web page address

http://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

Baghiatallah Salehi

Position

Student

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Bahonar Ave. Qazvin University of Medical Sciences

City

Qazvin

Province

Qazvin

Postal code

34197-59811

Phone

+98 28 3336 5001

Email

b.salehi@qums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Baghiatallah Salehi

Position

Student

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

University of Medical Sciences, Bahonar Blvd.,

City

Qazvin
Province
Qazvin
Postal code
34197-59811
Phone
+98 28 3336 5001
Email
b.salehi@qums.ac.ir

Qazvin
Province
Qazvin
Postal code
3419759811
Phone
+98 28 3333 8034
Email
b.salehi@qums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

بقیه اله صالحی

Position

Student

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Bahonar Blvd., Qazvin University of Medical Sciences,
Qazvin,

City

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

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

No - There is not 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