

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

The effect of tactile stimulation on vital signs and consciousness of traumatic brain injury patients hospitalized in intensive care units

Protocol summary

Summary

Objectives: This study aimed to investigate the effect of tactile stimulation on vital signs and consciousness of traumatic brain injury patients hospitalized in intensive care units. **Design:** This study was a quasi-experimental study with pretest- post test design that performed on 60 traumatic brain injury patients hospitalized in intensive care units (with Richmond scores of +2-+2) that underwent mechanical ventilation. **Method:** Intervention was applied with wrist and hand touching for 5 minutes. The GCS and vital signs (heart rate, respiration rate, temperature, systolic and diastolic blood pressure) were measured before and after intervention. **Inclusion criteria:** hospitalized with a diagnosis of head trauma; age from 18 to 65 years; no diagnosis of underlying disease such as diabetes (Neuropathy based on patient records); no upper limb disorders; no upper limb disorders; level of consciousness in the range of 5 to 8; no mental problems such as hallucinations or anxiety disorders. **Exclusion criteria:** no satisfaction to participate; move from Qazvin; a sharp drop in the level of consciousness suddenly. **Intervention:** Nurse touches around the patient's wrist and touching his hand slowly. The touching time is 5 minutes. The main outcome variables: measure the consciousness and vital signs of patients before and after tactile stimulation

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016062128563N1**

Registration date: **2017-06-09, 1396/03/19**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-06-09, 1396/03/19

Registrant information

Name

Fatemeh Aghaei

Name of organization / entity

Qazvin University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research of Qazvin University of Medical Sciences

Expected recruitment start date

2016-11-02, 1395/08/12

Expected recruitment end date

2017-03-05, 1395/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of tactile stimulation on vital signs and consciousness of traumatic brain injury patients hospitalized in intensive care units

Public title

The effect of tactile stimulation on vital signs and consciousness of traumatic brain injury patients hospitalized in intensive care units

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: The patient is hospitalized with a diagnosis of head trauma; Patient age ranged from 18 to 65 years; diagnosis of underlying disease such as diabetes (neuropathy due to possible based on patient records) is not; upper limb disorders in no sense; upper limb disorders in no sense; The patient's level of consciousness is in the range of 5 to 8; patient mental problems such as hallucinations or have anxiety disorders Exclusion criteria: patient dissatisfaction partners to continue to participate in the study; sample transport to other centers outside the city of Qazvin; a sharp drop in the level of consciousness suddenly; patients in both groups during the study and control at the same time patient care plans similar companies such as massage and relaxation techniques

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Using two-color balls in white (for control) and red (for intervention) for randomization.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Qazvin University of Medical Sciences

Street address

Qazvin - shahid Bamonar Blvd. - Qazvin University of Medical Sciences

City

Qazvin

Postal code

59811-34197

Approval date

2016-10-19, 1395/07/28

Ethics committee reference number

IR.QUMS.REC.1395.169

Health conditions studied

1

Description of health condition studied

head trauma Patients

ICD-10 code

S00-S09

ICD-10 code description

Injuries to the head

Primary outcomes

1

Description

level of consciousness

Timepoint

Before and after the intervention

Method of measurement

Using the Glasgow Coma Scale

Secondary outcomes

1

Description

vital sign

Timepoint

Before and after the intervention

Method of measurement

Using the monitoring -barometer-digital thermometer

Intervention groups

1

Description

Intervention group: Intervention in this case would be The intervention group, touch the wrist and the whole hand For 5 minutes, In the morning and evening for control group, all the routine cares will be delivered. Intervention will proceed in the first to the fifth day of hospitalization. Thus the 5 minutes before the intervention, researcher will be measured patient's vital signs, including blood pressure and pulse rate and respiration, body temperature and measure and record the patient's level of consciousness. Nurse fingers then gently placed around the patient's wrist without any Pressure. Time touching the patient's wrist and touch the whole hand is 5 minutes. Immediately after the intervention Again, vital signs and level of consciousness will be measured and recorded. This interference in the morning (11 am) and evening (17pm) for patients in this study was done.

Category

Treatment - Devices

2

Description

Control group:the control group, vital signs twice a day (at 11 am and 5 evenings) with an interval of 5 minutes, while rejecting any intervention on the patient.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rajai Hospital

Full name of responsible person

Dr. leily yekeh fallah

Street address

Shahid gharani street, Padegan street,Shahid Rajai Hospital, Qazvin

City

Qazvin

2

Recruitment center

Name of recruitment center

Zakaria raazi hospital

Full name of responsible person

Dr. leily yekeh fallah

Street address

After piped water supply channel, Shahid babaei street,Zakaria raazi hospital, Qazvin

City

Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Qazvin university of medical science

Full name of responsible person

Dr Leily Yekeh fallah

Street address

Shahid Bahonar blvd, Vice chancellor for research, Qazvin University of Medical Sciences, Qazvin

City

Qazvin

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 of Qazvin university of medical science

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

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr. Leily Yekeh fallah

Position

PhD in Nursing

Other areas of specialty/work

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Person responsible for scientific inquiries

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Senior student in intensive care

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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