Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 Jun 2026

The effectiveness of tactile stimulation on level of consciousness, pain, and physiological parameters in unconscious patients admitted to the intensive care

Protocol summary

Study aim

Comparing the effect of tactile stimulation hand and foot on consciousness, pain, and physiological parameters in unconscious patients admitted to the intensive care

Design

Single -blind clinical trial with block randomized allocation and parallel group design

Settings and conduct

The statistical population of this study are unconscious patients whose admit to the intensive care units of Shohadaye Tajrish Hospital. Assignment of patients to three groups is carried out by a statistical expert by using blocks. Each group includes 30 patients. Demographic and clinical characteristics of the patients are recorded with questionnaire. The hand tactile stimulation group receive touch for 10 minutes, twice a day for three days.The foot tactile stimulation group receive touch for 10 minutes, twice a day for three days.The control group don't receive any sensory stimulation.

Participants/Inclusion and exclusion criteria

Age range 18 to 60 years old; The level of consciousness based on Glasgow Coma Scale is less than 12; The Richmond Criteria in the range of 3- to 3+; Existence of pain in patients by CPOT criteria; Existence of normal brain CT; Hospitalization in ICU for the first time; The lack of history of mental illness; The lack of addiction; The lack of sensory-motor dysfunction in extremities; The lack of skin problems; The lack of diseases such as diabetes .

Intervention groups

The hand tactile stimulation group receive touch for 10 minutes, twice a day,for three days. The foot tactile stimulation group receive touch for 10 minutes, twice a day, for three days. The control group don't receive any sensory stimulation.

Main outcome variables

In each group the level of consciousness, physiological parameters, and pain will be evaluated before and after intervention during three days.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20110912007529N22**
Registration date: **2020-03-29, 1399/01/10**
Registration timing: **registered_while_recruiting**

Last update: **2020-03-29, 1399/01/10**
Update count: **0**

Registration date

2020-03-29, 1399/01/10

Registrant information

Name

Nahid Rejeh

Name of organization / entity

Shahed University

Country

Iran (Islamic Republic of)

Phone

+98 21 5121 3071

Email address

reje@shahed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-21, 1398/05/30

Expected recruitment end date

2020-04-16, 1399/01/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effectiveness of tactile stimulation on level of consciousness, pain, and physiological parameters in unconscious patients admitted to the intensive care

Public title

The effectiveness of tactile stimulation on unconscious patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Age range 18 to 60 years old The level of consciousness based on Glasgow coma scale is less than 12 The Richmond criteria in the range of 3- to 3+ Existence of pain in patients by CPOT criteria Existence of normal brain CT Hospitalization in ICU for the first time The lack of history of mental illness The lack of addiction The lack of sensory-motor dysfunction in the extremities The lack of skin problems The lack of diseases such as diabetes

Exclusion criteria:

Concurrent participation in similar care plans such as massage Use of receive neuromuscular blockers Severe disorders levels of consciousness

Age

From **18 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

The block randomization which the patient was the randomization unit. Assignment of patients to groups is carried out by a statistical expert. Block selection is based on the random number table.

Blinding (investigator's opinion)

Single blinded

Blinding description

Samplers and the statistical analyzer will be blind to patients ‘random allocation of the groups.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shaded University

Street address

Shahed University, Opposite to Holy Shrine of Imam Khomeini, Tehran-Qom Express way, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

3319118651

Approval date

2019-06-30, 1398/04/09

Ethics committee reference number

IR.SHAHEEED.REEC.1398.048

Health conditions studied

1

Description of health condition studied

comatose patient

ICD-10 code

B19.10

ICD-10 code description

Coma, unspecified

Primary outcomes

1

Description

Level of consciousness

Timepoint

Before and after intervention, twice a day, during three days

Method of measurement

The GCS and FOUR scores

2

Description

Intensity of pain

Timepoint

Before and after intervention, twice a day, during three days

Method of measurement

Critical Care Pain Observation Tool (CPOT)

Secondary outcomes

1

Description
Blood Pressure
Timepoint
Before and after intervention, twice a day, during three days
Method of measurement
The monitor used in Intensive Care Unit

2

Description
Respiratory Rate
Timepoint
Before and after intervention, twice a day, during three days
Method of measurement
The monitor used in Intensive Care Unit

3

Description
Heart Rate
Timepoint
Before and after intervention, twice a day, during three days
Method of measurement
The monitor used in Intensive Care Unit

4

Description
Oxygen Saturation
Timepoint
Before and after intervention, twice a day, during three days
Method of measurement
Pulse Oximeter

Intervention groups

1

Description
The first intervention group:The hand tactile stimulation group receive touch for 10 minutes, twice a day,11:00 am and 15:00 pm, for three days.
Category
Rehabilitation

2

Description
The second intervention group:The foot tactile stimulation group receive touch for 10 minutes, twice a day,11:00 am and 15:00 pm, for three days.
Category
Rehabilitation

3

Description
The control group don't receive any sensory stimulation.
Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Shohadaye Tajrish Hospital
Full name of responsible person
Maryam Ahmadi
Street address
Shohadaye Tajrish Hospital, Shahrdari St, Tajrish Square, Tehran
City
Tehran
Province
Tehran
Postal code
1989934148
Phone
+98 21 25719
Email
Pr_shohada@sbmu.ac.ir
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahed University
Full name of responsible person
Dr. Zahra Kiasalari
Street address
Shahed University, Opposite to Holy Shrine of Imam Khomeini, Tehran-Qom Express way, Tehran, Iran
City
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Postal code
3319118651
Phone
+98 21 5121 2150
Email
kiasalari@domain.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahed University
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

Shahed University

Full name of responsible person

Nahid Rejeh

Position

professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

Street address

Shahed University, Opposite to Holy Shrine of Imam Khomeini, Tehran-Qom Express way, Tehran, Iran

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All statistical data is available after being unidentifiable.

When the data will become available and for how long

The access period is up to one year after the publication of the results.

To whom data/document is available

Data is available to academic researchers.

Under which criteria data/document could be used

Use of information for academic research projects is allowed.

From where data/document is obtainable

Corresponding author; Shahed University, Opposite to Holy Shrine of Imam Khomeini, Tehran-Qom Express way, Tehran, Iran.

What processes are involved for a request to access data/document

Requests for specific information should be sent by an email to the responsible author along with an

explanation of why the data is needed.

Comments