

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

The effect of implementing sensory stimulations program on clinical outcomes of brain injury patients admitted in Intensive Care Unit

Protocol summary

Study aim

Determining the effect of implementing sensory stimulations program on clinical outcomes of brain injury patients admitted in ICU

Design

Clinical trial with control and parallel groups, without blindness, randomized

Settings and conduct

This study is a randomized trial that will be performed in Intensive care wards in Golestsn hospital of Ahvaz. The sample size is 66 people who will be divided into two groups of intervention by stratified randomization method and random number table. The study is not blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: The patient with brain injury is intubated and under ventilator; GCS score between 6 and 12; having pupillary reflex; Age between 18 and 67 years. Exclusion criteria: Having a history of mental illness and hospitalization in a mental hospital; More than 2 days have passed since the patient is admitted to the ICU; Having a history of debilitating underlying diseases such as kidney, heart and liver failure; History of alcohol and opioid addiction; Having delirium.

Intervention groups

Patients are divided into two groups. In the control group, they will be received the routine care, but in the intervention group, Sensory stimulations program will be implemented once a day and each time for 60 minutes during hospitalization in the intensive care unit. Intervention in the evening shift 16 to 17 will be implemented.

Main outcome variables

Type and Incidence rate of delirium, level of consciousness, Intensity of pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120414009469N4**
Registration date: **2021-05-08, 1400/02/18**
Registration timing: **prospective**

Last update: **2021-05-08, 1400/02/18**

Update count: **0**

Registration date

2021-05-08, 1400/02/18

Registrant information

Name

Mohammad Adineh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 1620 0140

Email address

mohadineh@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-06-21, 1400/03/31

Expected recruitment end date

2022-04-20, 1401/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of implementing sensory stimulations program on clinical outcomes of brain injury patients admitted in Intensive Care Unit

Public title

The effect of implementing sensory stimulations program on clinical outcomes of brain injury patients admitted in Intensive Care Unit

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

The patient with brain injury Intubated and under ventilator GCS score between 6 and 12 having pupillary reflex Age between 18 and 67 years.

Exclusion criteria:

Having a history of mental illness and hospitalization in a mental hospital; More than 2 days have passed since the patient is admitted to the ICU; Having a history of debilitating underlying diseases such as kidney, heart and liver failure; History of alcohol and opioid addiction; Having delirium

Age

From **18 years** old to **67 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **66**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, based on the inclusion and non-inclusion criteria, the participants are selected and then will be allocated randomly in two groups of intervention and control by Stratified randomization method. First, categories are created based on age group with an interval of 10 years (18 - 27, 28 - 37, 38 - 47, 47 - 57 and 58 - 67 years) and then in each category, a random sequence will be created by using a table of random numbers. In this way, after survey the patients in terms of inclusion criteria, each of them will have a number based on the order of inclusion in the study. These numbers will be selected using a random number table. The researcher will randomly place his hand on a point in the table of random numbers and then will separate the numbers in pairs from left to right. Numbers will be selected that fall within the sample size range. Even numbers will be considered for the intervention group and odd numbers for the control 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 Jundishapur Ahvaz University of Medical Sciences

Street address

Esfand St, Jundishapur University of Medical Sciences

City

Ahvaz

Province

Khuzestan

Postal code

61357-15794

Approval date

2021-04-10, 1400/01/21

Ethics committee reference number

IR.AJUMS.REC.1400.014

Health conditions studied**1****Description of health condition studied**

Head trauma

ICD-10 code

S06.3

ICD-10 code description

Focal traumatic brain injury

2**Description of health condition studied**

Head trauma

ICD-10 code

S06.2

ICD-10 code description

Diffuse traumatic brain injury

3**Description of health condition studied**

Head trauma

ICD-10 code

S06.4

ICD-10 code description

Epidural hemorrhage

4**Description of health condition studied**

Head trauma

ICD-10 code

S06.5

ICD-10 code description

Traumatic subdural hemorrhage

5**Description of health condition studied**

Head trauma

ICD-10 code

S06.6

ICD-10 code description

Traumatic subarachnoid hemorrhage

6**Description of health condition studied**

Brain Injury

ICD-10 code

S06

ICD-10 code description

Intracranial injury

Primary outcomes**1****Description**

Type and Incidence rate of delirium

Timepoint

During the patient's hospitalization in the ICU, Daily

Method of measurement

Confusion Assessment Method for the Intensive Care Unit (CAM-ICU)

2**Description**

severity of pain

Timepoint

5 minutes before intervention and 5 minutes after intervention

Method of measurement

Behavioral Pain Scale

3**Description**

consciousness level

Timepoint

5 minutes before intervention and 5 minutes after intervention

Method of measurement

Glasgow coma score

Secondary outcomes**1****Description**

Dependence on mechanical ventilation period

Timepoint

Number of days dependence on mechanical ventilation

Method of measurement

Checklist

2**Description**

Incidence rate of death

Timepoint

During hospitalization time

Method of measurement

Checklist

3**Description**

Hospitalization period in Intensive Care Unit

Timepoint

Number of days hospitalized in Intensive Care Unit

Method of measurement

Checklist

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

Intervention group: Sensory simulations program (Include: olfactory stimulation, auditory stimulation, Vision Stimulation, Tactile stimulation, Motor stimulation, awakening stimulation) will be implemented once a day, Between 4 and 5 p.m. and each time for 60 minutes during hospitalization in the intensive care unit.

Category

Other

2**Description**

Control group: There will be no intervention in the control group, and patients will be received routine care. In routine care, sensory stimulation is usually not performed for patients and there is no specific protocol for this.

Category

Other

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

Golestan Hospital

Full name of responsible person

Mohammad Adineh

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Golestan St. Golestan Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz University of Medical Sciences

Full name of responsible person

Mehdi Ahmadi Moghadam

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Email

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Grant name

3849

Grant code / Reference number

119

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Vice chancellor for research, Ahvaz Jundishapur 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

Ahvaz University of Medical Sciences

Full name of responsible person

Mohammad Adineh

Position

Instructor of Nursing

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

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Position

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Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

Name of organization / entity

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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

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

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

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

Title and more details about the data/document

All details of the data will be shared without the identification of the person being investigated by maintaining ethical principles.

When the data will become available and for how long

Start the access period immediately after publishing the results

To whom data/document is available

It will be accessible to everyone

Under which criteria data/document could be used

A certain condition will not be considered at this time.

From where data/document is obtainable

Researcher Email

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

Only by visiting the central library of Ahwaz University of Medical Sciences and providing a valid identification card will be available.

Comments