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)

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+98 66 1620 0140

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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
Khouzestan
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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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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 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
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