Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Jun 2026

The effect of planned sensory stimulation performed by family members and nurses on the level of consciousness ,vital signs and Oxygen saturation in patients admitted to Intensive care unit

Protocol summary

Study aim
investigation the effect of planned sensory stimulation performed by family members and nurses on the level of consciousness ,vital signs and Oxygen saturation in patients admitted to Intensive care unit

Design
This study is a double-blind clinical trial.The study population will be included all patients referring to the ICU of Imam Reza hospital in Kermanshah city.115 eligible patients will be selected conveniently and randomly assigned to three groups (two intervention and one control group)

Settings and conduct
This study, which will be carried out at Imam Reza Hospital in Kermanshah city a double-blind clinical trial, that the patients and the outcome evaluator were kept blind to the study groups and at the beginning of the study, the level of consciousness, vital signs, and arterial oxygen saturation in all three groups will be recorded in a checklist.

Participants/Inclusion and exclusion criteria
Inclusion criteria:The level of patients consciousness be between 6 and 12;The patient already has no history of mental illness, GCS fluctuations within a few days prior to the trauma (the Delirium term in this research) and admitted to a mental hospital Exclusion criteria:Patients get delirium;The patient will be fully aware after the recovery of disease

Intervention groups
The first intervention group will receive sensory stimulation by a family member every day for 2 hours, from 4 to 5 in the evening and 8 to 9 in night with 3 hours distance and for 6 days. The second intervention group will receive sensory stimulation by researcher every day for 2 hours, from 4 to 5 in the evening and 8 to 9 in night with 3 hours distance and for 6 days. Control group will not receive any sensory stimulation.

Main outcome variables
The level of consciousness, vital signs, and arterial oxygen saturation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20160308026961N5**
Registration date: **2018-07-04, 1397/04/13**
Registration timing: **registered_while_recruiting**

Last update: **2018-07-04, 1397/04/13**
Update count: **0**

Registration date
2018-07-04, 1397/04/13

Registrant information

Name
Shila Amini
Name of organization / entity
Kermanshah University of Medical Sciences
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-05-10, 1397/02/20

Expected recruitment end date
2018-07-11, 1397/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of planned sensory stimulation performed by family members and nurses on the level of consciousness ,vital signs and Oxygen saturation in patients admitted to Intensive care unit

Public title

The effect of planned sensory stimulation on the level of consciousness ,vital signs and Oxygen saturation in patients in patients admitted to the ICU

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Visitors are only the main members of the family (father, mother, spouse, child, sister, brother) and their age is over 18 years of age. Patients is hospitalized with head trauma (Types of brain hematomas and other lesions, except diffuse axon damage) The patient has pupil reflexes at the entrance to the ICU section. The level of patients consciousness be between 6 and 12 The patient already has no history of mental illness, GCS fluctuations within a few days prior to the trauma (the Delirium term in this research) It has not been more than 3 days passed since the patient's admitted to the Intensive Care Unit

Exclusion criteria:

History of admission to a psychiatric hospital Visitors younger than 18 years of age

Age

From **16 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **115**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients with stratified blocking method (based on the age group with 10 years distance, 16 to 25, 26 to 35, 36 to 45, 46 to 55, and 56 to 65) will be randomly divided into three groups and within each block, half of the intervening and half-blind individuals are considered as witnesses to balance the number of participants in each of the groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, patients and outcome evaluators will be blinded to the study groups

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Kermanshah University of Medical Sciences

Street address

Vice Chancellor for Research Affairs, Kermanshah University of Medical Sciences, Building No.2, Shahid Beheshti,

City

Kermanshah

Province

Kermanshah

Postal code

6715847141

Approval date

2016-11-23, 1395/09/03

Ethics committee reference number

kums.rec.1395.509

Health conditions studied

1

Description of health condition studied

Patients with head trauma

ICD-10 code

S09.9

ICD-10 code description

Unspecified injury of head

Primary outcomes

1

Description

the level of consciousness

Timepoint

10 minutes before the intervention and 30 minutes after the intervention

Method of measurement

Using the Glasgow Coma Scale (GCS)

2

Description

Vital signs

Timepoint

10 minutes before the intervention and 30 minutes after

the intervention

Method of measurement

Using a cardio-respiratory monitoring device and an oxilary thermometer

3

Description

Arterial oxygen saturation

Timepoint

10 minutes before the intervention and 30 minutes after the intervention

Method of measurement

Using a cardio-respiratory monitor

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group will receive sensory stimulation by a family member every day for 2 hours, from 4 to 5 in the evening and 8 to 9 in the night with 3 hours distance and for 6 days. Sensory stimulation program includes sight, auditory, smell, touch and kinesthetic stimulation. Olfactory stimulating by taking alcohol in front of the patient's nose for 5 seconds, sight stimulating by turning the flashlight on and off in front of the patient's eyes for 2 seconds,auditory stimulation by calling the patient's own name, time, place and day near the patient's ear three times,touch stimulating by squeezing and massage and rub the skin with cotton and guas, first, one side of the body and then the other side, kinesthetic stimulation by moving the joints of the hands and feet, the wrist, the hip joint and shoulder joint by bending and straightening, and alternating up and down the arms and legs 15 times, and each of the stimuli is performed once per hour

Category

Treatment - Other

2

Description

The second intervention group will receive sensory stimulation by researcher every day for 2 hours, from 4 to 5 in the evening and 8 to 9 in the night with 3 hours distance and for 6 days. Sensory stimulation program includes sight, auditory, smell, touch and kinesthetic stimulation. Olfactory stimulating by taking alcohol in front of the patient's nose for 5 seconds, sight stimulating by turning the flashlight on and off in front of the patient's eyes for 2 seconds,auditory stimulation by calling the patient's own name, time, place and day near the patient's ear three times,touch stimulating by squeezing and massage and rub the skin with cotton and guas, first, one side of the body and then the other side, kinesthetic stimulation by moving the joints of the hands and feet, the wrist, the hip joint and shoulder joint by bending and straightening, and alternating up and down the arms and legs 15 times, and each of the stimuli is performed once per hour

Category

Treatment - Other

3

Description

The control group will not receive any sensory stimulation.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Emam Reza Hospital

Full name of responsible person

Kamran Vafaee

Street address

Emam Reza Hospital, Parastar Boulevard

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research of Kermanshah University of Medical Sciences

Full name of responsible person

Dr. Farid Najafi

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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 Kermanshah 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
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Shila Amini
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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
Not applicable
Title and more details about the data/document
The main outcomes of the study will be shared.
When the data will become available and for how long
6 months

To whom data/document is available

If requested, results will be made available to other academic researchers

Under which criteria data/document could be used

Collected data is confidential and will not be shared with anyone else

From where data/document is obtainable

To receive the documentation, email send for update manager

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

In a 15-day period, the documents will be sent e-mail

Comments