

# 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

##### Country

Iran (Islamic Republic of)

##### Phone

+98 988138380320

##### Email address

sh.amini@edu.umsha.ac.ir

##### 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 oxillary 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 gas, 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 gas, 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 Vafaei

##### **Street address**

Emam Reza Hospital, Parastar Boulevard

##### **City**

Kermanshah

##### **Province**

Kermanshah

##### **Postal code**

6715847141

##### **Phone**

+98 83 3427 4609

##### **Email**

K.VAFABEE60@GMAIL.COM

## **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

##### **Street address**

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

##### **City**

Kermanshah

##### **Province**

Kermanshah

##### **Postal code**

6715847141

##### **Phone**

+98 83 3836 0014

##### **Email**

fnajafi@kums.ac.ir

#### **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**

Emam Reza Hospital

**Full name of responsible person**

Shila Amini

**Position**

Masters student of Nursing

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

Emam Reza Hospital, Parastar Boulevard

**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6715847141

**Phone**

+98 834276301

**Fax****Email**

k.vafaee1360@gmail.com

**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**

Emam Reza Hospital

**Full name of responsible person**

Kamran Vafaee

**Position**

Master of nursing

**Latest degree**

Master

**Other areas of specialty/work**

Nursery

**Street address**

Emam Reza Hospital, Parastar Boulevard

**City**

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**Province**

Kermanshah

**Postal code**

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**Phone**

+98 83 3427 6301

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k.vafaee1360@gmail.com

**Web page address****Person responsible for updating data****Contact****Name of organization / entity**

Emam Reza Hospital

**Full name of responsible person**

Shila Amini

**Position**

Masters student of Nursing

**Latest degree**

Master

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**City**

Kermanshah

**Province**

Kermanshah

**Postal code**

6715847141

**Phone**

+98 83 3427 6306

**Fax****Email**

sh.amini@edu.umsha.ac.ir

**Web page address****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**