

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

27 Jun 2026

### Effect of sensory stimulation programs on level of consciousness and Physiological parameters in patients with head injury in intensive care units

#### Protocol summary

##### Summary

This study aimed to investigate the effect of sensory stimulation program on the level of consciousness and physiological responses of patients with brain injury will be done. The study population included all patients admitted with a diagnosis of brain injury, Inclusion criteria: GCS less than 8, aged 15-65 years, the absence of sensory disorders in patients, and Exclusion criteria included : cerebral ischemia (confirmed by imaging studies), cardiac arrest, more than 4 minutes after admission. The sample consisted of 60 patients will be studied. The intervention involves the creation of various sensory stimulation for 6 days and 5 times per day will be two-hour intervals. Each intervention period lasts 30 minutes. Expected outcomes will be include changes in the level of consciousness after the intervention and changes in physiological variables, including: HR, RR, o2 SAT and systolic and diastolic blood pressure.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2014031116942N1**  
Registration date: **2015-11-25, 1394/09/04**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2015-11-25, 1394/09/04

##### Registrant information

###### Name

shiva monfared

###### Name of organization / entity

Kerman University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 34 1211 3025

##### Email address

sh.monfared@kmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Kerman University of Medical Sciences

##### Expected recruitment start date

2014-05-22, 1393/03/01

##### Expected recruitment end date

2015-01-20, 1393/10/30

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Effect of sensory stimulation programs on level of consciousness and Physiological parameters in patients with head injury in intensive care units

##### Public title

The effect of sensory stimulation on the level of consciousness and physiological parameters

##### Purpose

Supportive

##### Inclusion/Exclusion criteria

Inclusion criteria: diagnosis of head trauma, GCS 8 and less than 8, aged 15-65 years, the absence of sensory disorders in patients (impaired sense of hearing, sight, smell, touch and taste) Exclusion criteria included : cerebral ischemia (confirmed by imaging studies),

cardiac arrest, more than 4 minutes after admission

### Age

From **15 years** old to **65 years** old

### Gender

Both

### Phase

N/A

### Groups that have been masked

*No information*

### Sample size

Target sample size: **60**

### Randomization (investigator's opinion)

Randomized

### Randomization description

### Blinding (investigator's opinion)

Single 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 Kerman University of Medical Sciences

##### Street address

Tahmasebabad Crossroads, Kerman

##### City

kerman

##### Postal code

#### Approval date

2015-01-31, 1393/11/11

#### Ethics committee reference number

k/93/295

## Health conditions studied

### 1

#### Description of health condition studied

trumatic brain injury

#### ICD-10 code

S09.9

#### ICD-10 code description

For primary coding of intracranial injuries with associated fractures, reference should be made to the morbidity or mortality coding rules and guidelines in Volume 2.

## Primary outcomes

### 1

#### Description

level of Consciousness

#### Timepoint

Before and after each intervention.

#### Method of measurement

GCS and FOUR score

### 2

#### Description

blood pressure

#### Timepoint

Before and after each intervention.

#### Method of measurement

mm Hg and by cuff pressure of bed side monitoring device

### 3

#### Description

heart rate

#### Timepoint

Before and after each intervention.

#### Method of measurement

number / minute and by bed side monitoring device

### 4

#### Description

respiratory rate

#### Timepoint

Before and after each intervention.

#### Method of measurement

number / minute

### 5

#### Description

Arterial oxygen saturation

#### Timepoint

Before and after each intervention.

#### Method of measurement

In percentage terms, and by pulse oxymeter

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

For control group did not perform any intervention and Patients affected by normal environmental stimulations.

#### Category

Rehabilitation

### 2

#### Description

Interventions in intervention group is a program

consisted of sensory stimulation including :Tactile Gustatory, olfactory,auditory, visual and Kinetic Stimulation.Intervention done by the researcher for 6 days and 5 times per day.There is a 2-hour interval between the interventions.

**Category**

Rehabilitation

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

Ali ibn Abi Talib Hospital in Rafsanjan

**Full name of responsible person**

Shiva Monfared Parizi

**Street address****City**

Rafsanjan

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice chancellor for research,Kerman University of Medical Sciences ,Physiology Research Center

**Full name of responsible person**

Abass pardakhty

**Street address**

Physiology Research Center, Kerman University of Medical Sciences, Tahmassabad, Kerman

**City**

Kerman

**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,Kerman University of Medical Sciences ,Physiology Research Center

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin****Type of organization providing the funding**

*empty*

**Person responsible for general inquiries****Contact****Name of organization / entity**

Kerman University of Medical Sciences

**Full name of responsible person**

Hakimeh Hosseirezai

**Position**

Member of Kerman University of Medical Sciences

**Other areas of specialty/work****Street address**

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Kerman University of Medical Sciences

**Full name of responsible person**

Shiva Monfared parizi

**Position**

Critical Care Nursing Graduate

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

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**Position**

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**Web page address**

*empty*

## **Sharing plan**

**Informed Consent Form**

*empty*

**Deidentified Individual Participant Data Set (IPD)**

**Clinical Study Report**

*empty*

*empty*

**Study Protocol**

**Analytic Code**

*empty*

*empty*

**Data Dictionary**

**Statistical Analysis Plan**

*empty*