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, Tahmassbabad, 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

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Position

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Other areas of specialty/work

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Position

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Other areas of specialty/work

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty