

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Impact of sensory excitation performed by family members and nurses on the level of consciousness and vital signs in patients who are admitted to Intensive care unit and the general health of their families

Protocol summary

Summary

The patients who are admitted to Intensive care unit (ICU) are exposed to sensory deprivation. Studies have shown that sensory excitation has a positive effect on preventing sensory deprivation. However the role of family members in sensory stimulation, compared with nurses has not yet been studied. The goal of this study is to compare sensory excitation delivered by family members and nurses on the level of consciousness and vital signs in patients who are admitted to ICU and the general health status of their families in a clinical trial design. In this study 73 patients admitted to ICU (having head injury, GCS 6-12, age 16-65 years) will be randomly assigned into two test and one control groups. The first group will receive sensory excitation by family members (first-degree relatives, above 18 years old). The second group will receive sensory excitation by nurses and third group (control group) will receive no intervention. The intervention is Dying sensory excitation program. It will be applied two hours a day at 4-5 pm and 8-9 pm to the test groups for six days. For all subjects in these three groups, the level of consciousness and vital signs (Blood Pressure, Temperature, Respiratory Rate, and Pulse Rate) will be measured twice at 5 minutes before intervention and 30 minutes after intervention by the research assistant (a person other than the one who performs excitation). Family members general health status will be measured via interview before and after the 1st, 6th and 12th hourly intervention session in all groups using General Health Questionnaire (GHQ).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201204149469N1**
Registration date: **2012-06-30, 1391/04/10**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-06-30, 1391/04/10

Registrant information

Name

Mohammad Adineh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 66 1620 0140

Email address

mohadineh@gmail.com

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Lorestan University of Medical Sciences.

Expected recruitment start date

2012-03-20, 1391/01/01

Expected recruitment end date

2012-07-21, 1391/04/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Impact of sensory excitation performed by family members and nurses on the level of consciousness and vital signs in patients who are admitted to Intensive care

unit and the general health of their families

Public title

Impact of sensory excitation performed by family members and nurses on the level of consciousness and vital signs in patients who are admitted to Intensive care unit and the general health of their families

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria (patients): head injury - GCS 5 to 10 - age 16 to 65 years - obtained informed consent to participate in the study from family members,...

Exclusion criteria: discharge from the ICU before sixth day,.... Inclusion criteria (family members): first-degree relatives - older than 18 years,.... Inclusion criteria (nurses): Trained Nurses

Age

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

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **73**

Randomization (investigator's opinion)

Randomized

Randomization description

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 Lorestan university of medical sciences

Street address

Ethics Committee, Vice chancellor for research, Lorestan university of medical sciences.

City

Khorramabad

Postal code

381351698

Approval date

2012-05-13, 1391/02/24

Ethics committee reference number

20066375

Health conditions studied

1

Description of health condition studied

head trauma

ICD-10 code

S06.3, S06

ICD-10 code description

Focal brain injury, Epidural hemorrhage, Traumatic subdural hemorrhage, Traumatic subarachnoid hemorrhage, Intracranial injury with prolonged coma, Other intracranial injuries, Intracranial injury, unspecified

Primary outcomes

1

Description

Patient's consciousness level

Timepoint

5 minutes before intervention and 30 minutes after intervention

Method of measurement

Glasgow coma score

2

Description

Patient's vital signs

Timepoint

5 minutes before intervention and 30 minutes after intervention

Method of measurement

Respiratory-cardiac monitoring system

3

Description

Family members general health

Timepoint

immediately before and after the 1st, 6th and 12th hourly intervention session

Method of measurement

GHQ

Secondary outcomes

1

Description

Hospitalization period in ICU

Timepoint

Number of days hospitalized

Method of measurement

Checklist

Intervention groups

1

Description

Second test group patient: Dying sensory excitation program will be delivered by nurses. It will be applied two hours a day at 4-5 pm and 8-9 pm to the test groups for six days.

Category

Treatment - Other

2

Description

Control group patient: do not received Dying sensory excitation program, received Routine care.

Category

Treatment - Other

3

Description

First test group patient: Dying sensory excitation program will be delivered by family members. It will be applied two hours a day at 4-5 pm and 8-9 pm to the test groups for six days.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ashair hospital, ICU

Full name of responsible person

Mohammad Adinevand

Street address

Engelab st, Ashair hospitals.

City

Khoramabad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Lorestan university of medical sciences

Full name of responsible person

Dr. Mohammad Hassan Kayedi

Street address

Vice chancellor for research, Lorestan university of medical sciences.

City

Khorramabad

Grant name

124409010

Grant code / Reference number

1192

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor for research, Lorestan university of medical sciences

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

Lorestan university of medical sciences

Full name of responsible person

Mohammad Adinevand

Position

Postgraduate student, Master of nursing Sciences

Other areas of specialty/work

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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