

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Jun 2026

Comparison of the effect of auditory sensory stimulation with familiar and unfamiliar voices in level of consciousness of traumatic comatose patients admitted to ICU, educational and traputic centers of mazandaran university of medical sciences, 2011.

Protocol summary

Summary

This study is a double blind clinical trial (patient and assessor). The population includes 45 traumatic comatose patients with $GCS \leq 8$ with the age range of 15-75, admitted to ICU, training centers of mazandaran university of medical sciences. The sampling method allocated into three groups, one, two and the control. The test takes place among the patients with a tape recording of the voice, group one(stimulation with familial voice) and two (auditory stimulation by researcher introduced as a nurse), two times per day for 5-15 minutes. The control group, but the usual sounds of the environment, stimulation did not receive a hearing. Means of mMeasurement of consciousness of patients are the Glasgow Coma Scale(GCS) which controlled before, during and 2 minutes after the test takes place. These tests are meanwhile also take place for the control group. The time GCS, vital signs of patients were well controlled.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201109247537N1**
Registration date: **2012-06-07, 1391/03/18**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2012-06-07, 1391/03/18

Registrant information

Name

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Name of organization / entity

Mazandaran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Mazandaran University of Medical Sciences

Expected recruitment start date

2011-06-10, 1390/03/20

Expected recruitment end date

2011-12-11, 1390/09/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of auditory sensory stimulation with familiar and unfamiliar voices in level of consciousness of traumatic comatose patients admitted to ICU, educational and traputic centers of mazandaran university of medical sciences, 2011.

Public title

Auditory stimulation in level of consciousness of comatose patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: GCS \leq 8; traumatic comatose patient; aged between 15 To 75 years. Exclusion criteria: history of brain trauma; history of hearing loss; affection to diabet & cardiovascular disease& fat emboli; opium and drug addiction; otorrhea, Rhinorrhea; skull fracture or bleeding or surgery in temporal region andFracture or palsy in all organs or eyelid swelling.

Age

From **15 years** old to **75 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **45**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Vican Chancellor of Mazandaran University of Medical Science and Health Services

Street address

Moalem square, Moalem street, Sari, Mazandaran, IRAN

City

Sari

Postal code

4816715793

Approval date

2011-05-18, 1390/02/28

Ethics committee reference number

39-90

Health conditions studied

1

Description of health condition studied

Brain injury

ICD-10 code

S06.9

ICD-10 code description

Intracranial injury, unspecified

Primary outcomes

1

Description

Traumatic comatose patient level of consciousness

Timepoint

Before and between and after intervention 2 times per day till 14 days

Method of measurement

Glasgow Coma Scale

Secondary outcomes

empty

Intervention groups

1

Description

First group (stimulation with familial voice)2 times per day for 15 minutes till 14 day were stimulated

Category

Rehabilitation

2

Description

Second group (auditory stimulation by researcher introduced as a nurse) 2 times per day for 15 minutes till 14 day were stimulated.

Category

Rehabilitation

3

Description

The control group, but the usual sounds of the environment, stimulation did not receive a hearing

Category

Rehabilitation

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomains Hospital Sari

Full name of responsible person

Mohammad Ali Heydari Gorji

Street address

Mazandaran University of Medical Science- Nursing, Nasibeh Nursing and Midwifery School, Sari

City

Sari

2

Recruitment center

Name of recruitment center

Razi Hospital Ghaemshahr

Full name of responsible person

Mohammad Ali Heydari Gorji

Street address

Mazandaran University of Medical Science- Nasibeh
Nursing and Midwifery School, Sari

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research Vice Chancellor of Mazandaran University Of
Medical Science and Health Service

Full name of responsible person

Dr. Ahmad Ali Enayati

Street address

Moalem square; Moalem street

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Sari

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Research Vice Chancellor of Mazandaran University Of
Medical Science and Health Service

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

Mazandaran University of Medical Science and Health
Service

Full name of responsible person

Yadollah Jannati

Position

PhD./ Faculty Member

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empty

Sharing plan

Informed Consent Form

empty

Deidentified Individual Participant Data Set (IPD)

Clinical Study Report

empty

empty

Study Protocol

Analytic Code

empty

empty

Statistical Analysis Plan

Data Dictionary

empty