

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Aug 2026

Effect of structured auditory stimulation on the level of consciousness in patients' comatose in intensive care unit with head trauma admitted to hospital 5th Azar

Protocol summary

Summary

The purpose of this clinical trial is determining of the Effect of structured auditory stimulation on the level of consciousness in patients' comatose in intensive care unit with head trauma. The samples will be selected from comatose patients that would have admitted in the intensive care units of Panje Azar hospital of Gorgan , Iran. Then, the samples through an allocated randomizing Designed to case and control groups. The sample size is 40 head trauma comatose patients (20 interventional and 20 controls) that randomly allocated to the two groups. The study is double blind and Inclusion criteria are age of 15-60, GCS under 8 score, after 24 hours of admitting and after stabling of vital sign. Duration of intervention is 10 days and every day 3 times (in three shifts). Every auditory intervention is 15 minutes. A male nurse voice will be recorded and broadcasted for each patient as auditory stimulation. The content of auditory stimulation for each subject includes time, place, individual orientation, and individual demographic, family members' demographic and professional condition. The GCS of each subject is monitored and recorded before and 30 minutes after auditory stimulation by an educated nurse. Moreover, hemodynamic function is assessed such as pulse and respiratory rate, blood pressure before and after auditory stimulation. Also, in the subjects as control group all of them are monitored without auditory stimulation. the data compare through statistic tests.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012071810325N1**

Registration date: **2012-08-06, 1391/05/16**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-08-06, 1391/05/16

Registrant information

Name

Gholamreza Mahmoodi Shan

Name of organization / entity

Golestan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Golestan university of Medical sciences

Expected recruitment start date

2012-07-25, 1391/05/04

Expected recruitment end date

2012-10-06, 1391/07/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of structured auditory stimulation on the level of consciousness in patients' comatose in intensive care unit with head trauma admitted to hospital 5th Azar

Public title

Effect of structured auditory stimulation on the level of

consciousness in patients' comatose with head trauma

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: the admitted comatose patients in ICU with head trauma in the Panje Azar hospital of Gorgan , Iran who have the following criteria will be selected: GCS $\leq$ 8, no have disorder or decrease in auditory function, no heart arrested for 4 minutes or upper, no having Precedence of : convulsion, brain damage, cardiovascular disease, fatty embolism, Rhinorrhea, otorrhea, fracture of basal skull, hemorrhage or surgery in temporal. exclusion criteria:Early death (before 10 days, early discharge, disagreement of the responsible of patient for continuing of intervention, and auditory disorder.

Age

From **15 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **40**

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

Ethical committee of Golestan university of Medical sciences

Street address

Golestan university of Medical sciences; kilometer 2 Gorgan-sari ,Gorgan, Iran.

City

Gorgan

Postal code

4934172515

Approval date

2012-05-22, 1391/03/02

Ethics committee reference number

534/35/س

Health conditions studied

1

Description of health condition studied

comatose patients with head trauma

ICD-10 code

VI-S00-T98

ICD-10 code description

Diseases of the nervous system-injury, poisoning and certain other consequences of external causes

Primary outcomes

1

Description

level of consciousness

Timepoint

One time in each shift (3 times per 24 hours)

Method of measurement

GCS criteria

Secondary outcomes

1

Description

blood pressure

Timepoint

3 times in 24 hours

Method of measurement

blood pressure monitored based on mm Hg

2

Description

pulse

Timepoint

3 times in 24 hours

Method of measurement

pulse rate(counting) per minute

3

Description

respiratory rate

Timepoint

3 times in 24 hours

Method of measurement

counting respiratory rate per minute

4

Description

O2 saturation

Timepoint

3 times in 24 hours

Method of measurement

the percent of hemoglobine o2 saturatin

Intervention groups

1

Description

Duration of intervention is 10 days and every day 3 times (in three shifts). Every auditory intervention is 15 minutes. A male nurse voice will be recorded and broadcasted for each patient as auditory stimulation. The content of auditory stimulation for each subject includes time, place, individual orientation, and individual demographic, family members' demographic and professional condition.

Category

Prevention

2

Description

In the control group there is no intervention and patients receive standard care.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

5 Azar hospital

Full name of responsible person

Gholamreza Mahmoodi Shan

Street address

Golestan university of Medical sciences; kilometer 2 Gorgan-sari ,Gorgan, Iran.

City

Gorgan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research and technology, Golestan university of Medical sciences

Full name of responsible person

mohsen arabi

Street address

kilometer 2 Gorgan-sari ,Gorgan, Iran.

City

Gorgan

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 and technology, Golestan 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

Golestan University of Medical Sciences

Full name of responsible person

Gholamreza Mahmoodi Shan

Position

Doctoral(PhD)/Assistant professor

Other areas of specialty/work

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Person responsible for scientific inquiries

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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