

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Jun 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

###### Country

Iran (Islamic Republic of)

###### Phone

+98 17 1442 6900

###### Email address

mahmoudi@goums.ac.ir

##### 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/ک

## 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

##### Street address

kilometer 2 Gorgan-sari ,Gorgan, Iran.

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##### Phone

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##### Web page address

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Golestan University of Medical Sciences

##### Full name of responsible person

Gholamreza Mahmoodi Shan

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## Person responsible for updating data

### Contact

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Gholamreza Mahmoodi Shan

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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*