

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

The effect of Organized auditory stimulation with familiar voices on the level of consciousness and hemodynamic status of coma patients hospitalized in intensive care unit

Protocol summary

Summary

The purpose of this clinical trial is determining of The effect of Organized auditory stimulation with familiar voices on the level of consciousness and hemodynamic status of coma patients hospitalized in intensive care in PourSina hospital 92-93. The samples will be selected from comatose patients that would have admitted in the intensive care units of PourSina hospital of Rasht ,Iran. Then, the samples through an allocated randomizing Designed to case and control groups. The sample size is 60 head trauma comatose patients (30 interventional and 30 controls) that randomly allocated to the two groups. In this study Inclusion criteria are age of 16 above, GCS under 8 score in head trauma patients, Stable vital signs 24 hours after admission and duration of coma less than 72 hours. Duration of intervention is 3 days and every day 1 times (in afternoon shifts). Every auditory intervention is 10 minutes that after identifying a person of interest to the patient, will be recorded his/her voice in a quiet place and and broadcasted for each patient as auditory stimulation. The content of auditory stimulation for each subject includes: The Person introduces himself and aware patient of the time and place, Briefly explain to the patient what has happened to him/her, Then the sweet memories shared and hopeful, optimistic and encouraging in terms of improved patient returned to his family and future plans will be discussed. The GCS of each subject is monitored and recorded 5 minutes before and 5 minutes after auditory stimulation and hemodynamic function is assessed such as pulse and respiratory rate, blood pressure, mean arterial pressure, Temperature, 2 minutes before and 2 minutes after auditory stimulation by a researcher. 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: **IRCT2014051517693N1**
Registration date: **2014-08-14, 1393/05/23**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-08-14, 1393/05/23

Registrant information

Name

Mohammad Reza Yeganeh

Name of organization / entity

Guilan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 13 1555 5056

Email address

yeganeh@gums.ac.ir

Recruitment status

Recruitment complete

Funding source

Guilan University of Medical Sciences

Expected recruitment start date

2014-06-22, 1393/04/01

Expected recruitment end date

2014-11-21, 1393/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Organized auditory stimulation with familiar voices on the level of consciousness and hemodynamic status of coma patients hospitalized in intensive care unit

Public title

The effect of Organized auditory stimulation with familiar voices on the level of consciousness and hemodynamic status of coma patients

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: the admitted comatose patients in ICU with head trauma in the PourSina hospital of Rasht , Iran who have the following criteria will be selected: GCS \leq 8, Artificial airway (endotracheal tube - the mouth or nose - or tracheostomy), 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 or discharge (before 3 days),Hemodynamic changes during intervention(A sudden increase or decrease in systolic and diastolic pressures over mmhg 20 compared to baseline,A sudden increase or decrease in heart rate over 20 beats to the base,Increased respiratory rate more than 25 and decreased more than 8 times per minute compared to the baseline)

Age

From **16 years** old to **139 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)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Guilan University of Medical Sciences

Street address

Gillan - Rasht - Namjoo Street - opposite Azodi Stadium - Gilan University of Medical Sciences

City

Rasht

Postal code

65385-41446

Approval date

2014-07-07, 1393/04/16

Ethics committee reference number

2930162909

Health conditions studied

1

Description of health condition studied

Head Trauma,Brain injury,Intracranial injury

ICD-10 code

S09.7,S09.

ICD-10 code description

Multiple injuries of head,Other specified injuries of head,Intracranial injury

Primary outcomes

1

Description

level of consciousness

Timepoint

Once a day for three consecutive days

Method of measurement

GCS criteria

Secondary outcomes

1

Description

blood pressure

Timepoint

Once a day for three consecutive days

Method of measurement

blood pressure monitoring based on mm Hg

2

Description

Pulse

Timepoint

Once a day for three consecutive days

Method of measurement

pulse rate(counting) per minute by monitoring

3

Description

respiratory rate

Timepoint

Once a day for three consecutive days

Method of measurement

respiratory rate counting per minute

4

Description

body temperature

Timepoint

Once a day for three consecutive days

Method of measurement

With axillary thermometer based on C

Intervention groups

1

Description

Organized auditory stimuli in the intervention group for 3 days, Once daily (evening shift) for 10 minutes With the voice of a person of interest to the patient becomes sick auditory stimulation. The content of auditory stimulation for each subject includes: awareness about the location, time, Briefly explain to the patient what has happened to him/her, Then the sweet memories shared and hopeful, optimistic and encouraging in terms of improved patient returned to his family and future plans will be discussed

Category

Prevention

2

Description

The control group did not receive intervention

Category

N/A

Recruitment centers

1

Recruitment center**Name of recruitment center**

Rasht Poursina Hospital

Full name of responsible person

Mohammad Reza Yeganeh

Street address

Guilan, Rasht, Namjo street- Porsina Hospital

City

Rasht

Sponsors / Funding sources

1

Sponsor**Name of organization / entity**

Vice-Chancellor for Research of Guilan University of Medical Sciences

Full name of responsible person

Abtin Heidarzadeh

Street address

Shahid Beheshti Blvd. , Vice-Chancellor for Research of Guilan University of Medical Sciences

City

Rasht

Grant name

ندارد

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

Yes

Title of funding source

Vice-Chancellor for Research of Guilan 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**

Guilan University of Medical Sciences

Full name of responsible person

Mohammad Kazem Mohammadi

Position

MS of Critical care student (MSc)

Other areas of specialty/work**Street address**

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MS in Nursing

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