Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Effect of Organized Auditory Stimulation on Pain Intensity and Physiologic Indices in Comatose Patients in Intensive Care Unit

Protocol summary

Summary

This research is a randomized clinical trial with the aim of determining the effect of organized auditory stimulation with familiar sound to the pain and physiological indices of coma patients tha was conducted in ICU wards of Shahid Kamiyab Hospital in 2017 in 40 patients with intubation who had the criteria for entering the study and were selected easily and conveniently and randomly divided into two groups of 20 (Control and test) were performed. In the experimental group, auditory stimulation with familiar voice was performed for 3 consecutive days and 15 minutes each day by headphones and in the intervention group without auditory stimulation, pain was recorded before and after the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017072035196N1**
Registration date: **2017-09-17, 1396/06/26**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-09-17, 1396/06/26

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Research Deputy of Gonabad University of Medical Sciences

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2017-08-22, 1396/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Organized Auditory Stimulation on Pain Intensity and Physiologic Indices in Comatose Patients in Intensive Care Unit

Public title

The effect of organized auditory stimulation with familiar sounds on pain and physiological indices in Comatose Patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: Age of 18 to 50 years old; Head trauma with a level of consciousness between 5 to 8 based on Glasgow's scale; Pain with at least 5 scores based on measurement with Behavior Pain Scale; Artificial airway (tracheal tube or tracheostomy); Duration of coma up to 48 hours at the start of the survey; Absence of hearing impairment, neuromuscular and sensory-motor disorders; Non-breakage or paralysis of all organs
Exclusion criteria: Brain death; Death or discharge from the Intensive Care Unit; Extubation of the patient;

Increasing the dose of sedative and anesthetic drugs during the study

Age

From **18 years** old to **50 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

Research Ethics Committee of Gonabad University of Medical Sciences

Street address

Next to the Asian Road, Educational and Research Deputy of Gonabad University of Medical Sciences

City

Gonabad

Postal code

9691793718

Approval date

2017-03-14, 1395/12/24

Ethics committee reference number

IR.GMU.REC.1395.120

Health conditions studied

1

Description of health condition studied

Pain

ICD-10 code

R52.9

ICD-10 code description

Generalized pain NOS

Primary outcomes

1

Description

Pain

Timepoint

Before and after intervention

Method of measurement

Behavior Pain Scale

2

Description

Blood pressure

Timepoint

Before, during and after the intervention

Method of measurement

Monitoring device

3

Description

Pulse

Timepoint

Before, during and after the intervention

Method of measurement

Monitoring device

4

Description

Body temperature

Timepoint

Before, during and after the intervention

Method of measurement

Monitoring device

5

Description

Arterial oxygen saturation

Timepoint

Before, during and after the intervention

Method of measurement

Monitoring device

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Intraocular stimulation of a person with familiar voice, 3 consecutive days and 15 minutes each day with headphones.

Category

Treatment - Other

2

Description
Control group: Putting the headphones on the ears of the control group (no audible stimulation)
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Kamyab Hospital
Full name of responsible person
Amir Khojeh Student of master degree in critical care nursing
Street address
Street of Fadaiyan Islam, Nakhrisi Crossroad
City
Mashhad

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Research Deputy of Gonabad University of Medical Sciences
Full name of responsible person
Dr. Ali Mohammad Pour Vice chancellor for research
Street address
Next to the Asian Road
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Research Deputy of Gonabad 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

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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