

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Auditory stimulation by family voices and recitation of prayers on consciousness level and hemodynamic changes of comatose patients

Protocol summary

Summary

Objectives: Traumatic Brain Injuries is one of the major causes of death and disability around the world. Recently to improve the results of the coma, coma stimulation techniques is suggested. Accordingly, the aim of this study was to compare the effect of hearing a familiar voice and the Azan sound in level of Consciousness and Hemodynamic Parameters. Design: this study is a clinical trial with pre and post test design. Setting and conduct: 51 Patients with coma randomly divided in 3 groups: Familiar sound group (n=18), Azan group (n=18) and Control group (n=15). Inclusion criteria for this study included: Comatose traumatic patients; Muslim patients; Ages range from 68-14 years; Levels of consciousness 8 and less than 8 Exclusion criteria included: patient died before day 14 in both groups; Swelling of both eyelids; Changes in the patient's condition so that the possibility of intervention, such as sending a patient away to another hospital, cardiac arrest Intervention: Familiar sound group, 14 days, 2 time a day, afternoon and evening prayers, the voice of one of his relatives received. Azan group received the same way azan sound. Before and after each intervention level of Consciousness and Hemodynamic Parameters were recorded. level of Consciousness and Hemodynamic Parameters was recorded in the same way in control group, twice a day, without any intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014081418794N1**

Registration date: **2015-02-23, 1393/12/04**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-02-23, 1393/12/04

Registrant information

Name

Fatemeh Mogaddam

Name of organization / entity

Zanjan University of Medical Science

Country

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Zanjan University of Medical Sciences

Expected recruitment start date

2013-06-24, 1392/04/03

Expected recruitment end date

2013-12-24, 1392/10/03

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Auditory stimulation by family voices and recitation of prayers on consciousness level and hemodynamic changes of comatose patients

Public title

Auditory stimulation in comatose patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria for this study included: Comatose traumatic patients; Muslim patients; Ages range from 68-14 years; Levels of consciousness 8 and less than 8; No fracture and surgery for temporal lobe; The lack of swelling of both eyelids; Absence of severe mental illness; Absence of Fracture four limbs; Family consent for participation in the study; The absence of hearing loss. Exclusion criteria included: patient died before day 14 in both groups; Swelling of both eyelids; Changes in the patient's condition so that the possibility of intervention , such as sending a patient away to another hospital, cardiac arrest.

Age

From **14 years** old to **68 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **51**

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

Ethics Committee, Zanjan University of Medical Science

Street address

Zanjan University of Medical Sciences, Beginning of the Islamic Republic of Iran, Azadi Square, Zanjan

City

Zanjan

Postal code

Approval date

2013-06-17, 1392/03/27

Ethics committee reference number

zums.rec.1392.42

Health conditions studied

1

Description of health condition studied

Traumatic Brain Injury

ICD-10 code

S06.0, S06

ICD-10 code description

Intracranial injury

Primary outcomes

1

Description

Level of Consciousness

Timepoint

pre and post intervention

Method of measurement

GCS Scale

2

Description

Hemodynamic Status

Timepoint

pre and post intervention

Method of measurement

Monitoring sistem and Termometer

Secondary outcomes

empty

Intervention groups

1

Description

Patient familiar voice was recorded with mp3 by Mark Marshall. This sound contains was introduction to a patient, slight accident occurred and reassuring messages. Sounds were delivered through headphones to listen to the patient. Before using for the patient controlled louder volume by researcher to patient does not hurt. Sound familiar twice a day for two weeks, in time for afternoon prayer and the sunset in the patients was born into group.Sounds duration of about 3 to 5 minutes. Before and after intervention in group consciousness level and hemodynamic variables were recorded.

Category

Other

2

Description

The sound of the call to prayer of the muezzin's voice was born. The call duration is approximately 4 minutes that 14 days this sound like a familiar voice, twice daily at noon and evening prayer for the patient by headphone. Before and after the intervention of consciousness and hemodynamic variables were recorded.

Category

Other

3**Description**

The control group did not receive any intervention by the researcher. It's just routine hearing voices. In this group, twice daily for 14 days, Level of consciousness and hemodynamics were recorded.

Category

Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Ayatollah Mousavi Hospital

Full name of responsible person

Fatemeh Mogaddam

Street address

Ayatollah Mousavi Hospital, Road Gavazng, Zanzan

City

Zanzan

2**Recruitment center****Name of recruitment center**

Emdadi Hospital Abhar

Full name of responsible person**Street address****City**

Abhar

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Medical Sciences Vice Chancellor for Research,
Zanzan University of Medical Science

Full name of responsible person

Sograt Faghihzadeh

Street address

Zanzan University of Medical Sciences, Beginning of
the Islamic Republic of Iran, Azadi Square, Zanzan

City

Zanzan

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

Yes

Title of funding source

Medical Sciences Vice Chancellor for Research, Zanzan
University of Medical Science

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**

Zanzan University of Medical Science

Full name of responsible person

Fatemeh Mogadam

Position

Master

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Full name of responsible person

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Position

Asistant

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

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Web page address**Person responsible for updating data****Contact**

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