Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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

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Name of organization / entity

Zanjan University of Medical Science

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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
SO6.0, SO6

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, Zanjan
City
Zanjan

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, Zanjan University of Medical Science
Full name of responsible person
Sograt Faghihzadeh
Street address
Zanjan University of Medical Sciences, Beginning of the Islamic Republic of Iran, Azadi Square, Zanjan
City
Zanjan
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, Zanjan 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
Zanjan University of Medical Science
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Person responsible for scientific inquiries

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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