Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

The effect of pleasant sound stimulation on hemodynamic parameters, the agitation and level of Consciousness in comatose patient in Intensive Care Units

Protocol summary

Study aim

This study aimed to determine the effect (impact) of pleasant sound stimuli on hemodynamic parameters, restlessness and level of alertness in comatose patients hospitalized in Intensive Care Units in educational hospitals of Kermanshah.

Design

This interventional study is a one-blind randomized clinical trial. Based on the criteria for entering the study, 80 samples were selected purposefully and with a probability of dropping out and then randomly assigned to the intervention and control groups using packets in the package of patients.

Settings and conduct

This study was performed on chest patients admitted to intensive care units of educational hospitals in Kermanshah. this interventional study is a randomized, one-blind clinical trial .patients' packets will be assigned to two groups of intervention and control. the intervention was performed by the first collaborator and due to the insertion of headphones in the two groups, the second researcher would be unaware of the separation of the groups.

Participants/Inclusion and exclusion criteria

Entrance criteria: Alert level less than 8 years- Non use of antidepressants and stimulants- Anti-inflammatory drugs and- No previous brain damage- Lack of Exit of cerebrospinal fluid or blood from the ear and nose- Failure of fracture, bleeding and temporal and temporal regional surgery- Absence of fracture in four limbs or quadriplegia- No severe changes in intracranial pressure. Exit criteria: Discharge or death of the patient before 6 day- Dislav the patient from continuing the study- Severe changes in vital signs- Severe changes in mental status- Interruption of brain stem reflex during research.

Intervention groups

The method of intervention in the intervention group will be that a detailed account of the psychological field and the individual's interest in the particular voice will be taken. According to the description of the patient's companions, the type of intervention includes music with or without words, the voice of the Holy Quran, Tavashish, the voice of a person of interest from the family members of the patient and etc will be specified. Daily intervention in the shift in the evening hours of 17-15 is due to a lack of disturbing sensory stimuli for 10 minutes. The actions taken in the control group will be such that, after obtaining written consent from the patient's guardian for participation in the study as a control group, there will be only a non-acoustic headphone during the study for the patient. At the same time as the intervention group, hemodynamic indices and restlessness were recorded immediately and 10 minutes later during the study.

Main outcome variables

Hemodynamic parameters include heart rate, respiratory rate, systolic and diastolic blood pressures, mean blood pressure, pulse pressure, arterial oxygen saturation, and Richmond Agitation-Sedation Scale Questionnaire for measuring restlessness and using Glasgow criteria for measuring the level of consciousness of the samples Before and immediately and 10 minutes after intervention.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171024036979N1**
Registration date: **2017-12-08, 1396/09/17**
Registration timing: **prospective**

Last update: **2017-12-08, 1396/09/17**
Update count: **0**

Registration date

2017-12-08, 1396/09/17

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kurdistan University of Medical Sciences

Expected recruitment start date

2017-12-11, 1396/09/20

Expected recruitment end date

2018-02-20, 1396/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of pleasant sound stimulation on hemodynamic parameters, the agitation and level of Consciousness in comatose patient in Intensive Care Units

Public title

The effect of pleasant sound stimulation on hemodynamic parameters, the agitation and level of Consciousness in comatose patient

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Alertness level equal to and less than 8 according to Glasgow Patients aged 15-75 years 24Hours after vital signs are sustained in the intensive care unit Not taking antidepressants or affecting restlessness and tranquilizers and Opiums Absence of mental disorders No previous brain damage No impairment or hearing loss Lack of cerebrospinal fluid or blood from the ears and nose Non-fracture, bleeding and temporal and temporal area surgery No addiction Not getting cancer Lack of fracture in four limbs or quadriplegic No significant changes in intracranial pressure

Exclusion criteria:

Discharge or death of the patient before day 6 Cancellation of the patient's continuation of the study Severe changes in vital signs Severe changes in mental status Severe changes in intracranial pressure Destruction of brain stem reflex during research

Age

From **15 years** old to **75 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Outcome assessor

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients eligible for 2 randomized intervention and control groups will be assigned randomly, using packets in envelopes, envelopes 1 for intervention and 2 for control.

Blinding (investigator's opinion)

Single blinded

Blinding description

To blind the study, the first research assistant intervened and due to wearing headphones in the two groups the second researcher would not be able to differentiate between the intervention group and control group. After wearing headphones, regardless of the type of group, he will collect the information.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic committee of Kurdistan University of Medical Sciences

Street address

Kurdistan University of Medical Sciences, after Qods Hospital, Sanandaj

City

Sanandaj

Province

Kurdistan

Postal code

13446-66177

Approval date

2017-10-07, 1396/07/15

Ethics committee reference number

IR.MUK.REC.1396/176

Health conditions studied

1

Description of health condition studied
Coma
ICD-10 code
R40.2
ICD-10 code description
Unconsciousness NOS

Primary outcomes

1

Description
Hemodynamic parameters
Timepoint
Before, immediately and ten minutes after the intervention
Method of measurement
Systole and diastolic blood pressure with mercuric pressure gauge, moderate blood pressure with the corresponding formula, pulse pressure by decreasing systole pressure from diastol, oxygen saturation with plusoxymmeters

2

Description
Agitation
Timepoint
Before, immediately and ten minutes after the intervention
Method of measurement
Using Richmond Agitation-Sedation Scale (RASS)

3

Description
level of consciousness
Timepoint
Before, immediately and ten minutes after the intervention
Method of measurement
Using the Glasgow coma scale (GCS)

Secondary outcomes

empty

Intervention groups

1

Description
Control group: In this group, headphones are worn by patients (with playing no sound) without any other stimuli for 10 minutes for a week.
Category
Other

2

Description
Intervention group: In this group, sound stimuli pleasant for patients are played for 10 minutes for one week with headphones without any other stimuli.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Reza hospital
Full name of responsible person
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Student Research Committee, Vice Chancellor for research and technology of Kurdistan University of M
Full name of responsible person
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Grant name
بودجه عمومی
Grant code / Reference number
304
Is the source of funding the same sponsor

organization/entity?
Yes
Title of funding source
Student Research Committee, Vice Chancellor for research and technology of Kurdistan University of M
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Vice Chancellor for research and technology of Kurdistan University of Medical Sciences
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Position
Master of Nursing / Student
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available