Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Study of nature music effect on Delirium incidence in post Coronary Artery Bypass Graft (CABG) surgery patients a controlled randomized clinical trial

Protocol summary

Study aim

Determination nature music effect on Delirium incidence in post Coronary Artery Bypass Graft (CABG) surgery patients.

Design

Randomized trial, parallel with control group, two blind sides design for 100 patients, using blocking for randomization

Settings and conduct

This study will take place in Isfahan Milad hospital'sI Intensive Care Unit (ICU). After admission of patients in the ICU and extubation, they will test by Confusion Assessment Method-ICU (CAM-ICU) and if the result is negative and the whisper test is positive, they will enter the study. In order to blinding, a medical student will do the CAM-ICU test two times a day and the intervention will take place by an ICU nurse. the nurse will play the one hour music with a headphone two times a day for 2 days.

Participants/Inclusion and exclusion criteria

Patients who are post Coronary Artery Bypass Graft (CABG) and assent to participation and age less than 75 will enter to our study; if they have any history of psychological disorders, cerebrovascular accident or hepatic or renal failure, history of any drug and alcohol abuse, who have prescribed special drugs which can cause delirium in operation room or Intensive Care Unit (ICU) and special condition which can cause central nervous system hypoxemia in operation room, patients who have positive delirium test after operation room, can not enter the study.

Intervention groups

Samples divide randomly in intervention and control groups; We play two one hour music sessions each day for 2 days by a headphone. In control group we don't play any music.

Main outcome variables

Delirium incidence will measure by Confusion Assesment Method-Intensive Care Unit (CAM-ICU) test; Changes in Richmond Agitation Sedation Scale (RASS) score mean after and befor intervention; ICU hospitalization time mean; Vital signs and Atrial Blood Gas parameters means in both groups.

General information

Reason for update

Data collection have been finished.

Acronym

IRCT registration information

IRCT registration number: **IRCT20200608047693N1**
Registration date: **2020-06-23, 1399/04/03**
Registration timing: **prospective**

Last update: **2021-07-02, 1400/04/11**
Update count: **1**

Registration date

2020-06-23, 1399/04/03

Registrant information

Name

Fatemeh Esfahanian

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-06-21, 1399/04/01

Expected recruitment end date
2021-08-23, 1400/06/01
Actual recruitment start date
2020-10-26, 1399/08/05
Actual recruitment end date
2021-06-20, 1400/03/30
Trial completion date
2021-06-20, 1400/03/30

Scientific title
Study of nature music effect on Delirium incidence in post Coronary Artery Bypass Graft (CABG) surgery patients a controlled randomized clinical trial

Public title
Effect of nature sound on consciousness after open Heart surgery
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Post CABG patients Patients who assent to participation in the study Patients who their auditory status are confirmed by Whisper test Patients under 75 years old
Exclusion criteria:
Patients with history of CVA Patients who have prescribed Ketamine or Midazolam in operation room or Benzodiazepine , Hallopridol or Propofol in ICU Patients who have mean perfusion pressure less than 70 mmHg during operation Patients who have more than 88 minutes clamp time Patients who have more than 142 minutes cardiopulmonary pomp during operation Patients who have second operation during CABG according to operation report Patients who have drug addiction Patients who have positive CAM-ICU after operation room Patients who have history of renal failure or cirrhosis Patients with anti-psychotic or psychedelic drugs history Patients who are alcoholism Patients with Major Depression disorder who have acceptable Beck Depression Inventory score Patients with history of Dementia
Age
To **74 years** old
Gender
Both

Phase
3
Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **100**
Actual sample size reached: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
In order to randomize our samples we use random sequence (Blocking) by Excel; We use 4 blocks to equal two groups for entrance the study. Blocks are chosen from samples and fall in group A or B by Excel; In the end we will decide one the groups to be the control and the intervention.
Blinding (investigator's opinion)
Double blinded
Blinding description
In order to blind the study we choose different person from ICU nurses to perform the intervention; The main researcher who will do the finale test will be different and cant contact the nurses. Our data analyzer will not informed about the patients groups and finally the patients will have information about their groups.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences
Street address
Isfahan University of Medical sciences., Hezarjarib St., Azadi Sq
City
Isfahan
Province
Isfehan
Postal code
8174673461
Approval date
2020-05-09, 1399/02/20
Ethics committee reference number
IR.MUI.MED.REC.1399.115

Health conditions studied

1

Description of health condition studied
Post CABG delirium
ICD-10 code
F05
ICD-10 code description
Delirium due to known physiological condition

Primary outcomes

1

Description
Delirium incidence according to CAM-ICU test result
Timepoint
Checking delirium CAM-ICU test before intervention and

at 3 and 9 p.m. daily

Method of measurement

Confusion Assessment Method for the Intensive Care Unite score

Secondary outcomes

1

Description

RASS core mean before and after intervention

Timepoint

Before intervention and at 3 and 9 p.m. dailykl

Method of measurement

Richmond agitation and sedation scale

2

Description

Difference in ICU hospitalization mean time in both groups

Timepoint

At the end of ICU hospitalization

Method of measurement

ICU hospitalization hours

3

Description

Difference in vital signs mean between two groups

Timepoint

In period of 3 p.m. to 8 p.m. and 9 p.m. to 2 p.m.

Method of measurement

Heart rate, respiratory rate and blood pressure

4

Description

Difference in ABG parameters means in both groups

Timepoint

In period of 3 p.m. to 8 p.m. and 9 p.m. to 2 p.m.

Method of measurement

Chemical results for pco2(partial pressure of carbon dioxide), po2 (partial pressure of oxygen), ph(potential hydrogen) and base excess

Intervention groups

1

Description

Intervention group: We play 9 tracks of nature sound which their names areA Deer in the distance by Stuart Jones ، Cool Forest Rain ، A calming cadence ، Driftwood ، Calm the mind ، Spirit wind و Ankgor Wat by Dan Gibson ، joyful tweet by Serenity Nature Sounds Academy و Rock of Ages by Steve Wingfield at 2 and 8 p.m. The tracks will be playes by a headphone with 10% volume, low tempo(60-80 bpm) and 440-470 KHz frequency. Before intervention and after each music sessions we will do Confusion Assessment Method-Intensive Care Unit and meanwhile we will check vital signs and blood gas.

Category

Prevention

2

Description

Control group: In this group we only will check their vital signs, blood gases and Confusion Assessment Method-Intensive Care Unit test.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Milad hospital

Full name of responsible person

Fatemeh Esfahanian

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

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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

Esfahan University of Medical Sciences

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
Esfahan University of Medical Sciences

Full name of responsible person
Fatemeh Esfahanian

Position
Medical student

Latest degree
Medical doctor

Other areas of specialty/work
General Surgery

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Person responsible for updating data

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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