

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effect of Holy Quran Voice on delirium prevention after cardiac surgery

Protocol summary

Study aim

Investigate the effect of Holy Quran voice on prevention of delirium after cardiac surgery.

Design

This study has intervention and control groups and is blind on one side. The sample size predicted for this study is 108 people and will be randomized into blocks

Settings and conduct

In this randomized clinical trial, 108 patients with cardiac surgery referred to Golestan Hospital in Ahvaz in 2018 will be selected using the consecutive sampling and randomly assigned into groups of experimental and control. In the intervention group, the voice of Quran plays twice daily for 10 minutes each time. Patients are evaluated twice daily for Delirium. In the control group, routine care will be performed. Blind study will be done using a research fellow. So that the researcher who has the task of evaluating the outcome is not informed about the allocation of patients.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Age of 18 to above; having the orientation to time, place, person; Being Muslim; Lack of mental disorders; Talking in Farsi Exclusion criteria: Alcoholism or substance abuse; having a hearing problem; not having the consent to enter the study

Intervention groups

In the intervention group, the voice of the Quran plays twice daily for 10 minutes each time. Patients are evaluated twice daily for Delirium. In the control group, routine care is performed.

Main outcome variables

Delirium

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171222037990N1**

Registration date: **2018-11-27, 1397/09/06**

Registration timing: **registered_while_recruiting**

Last update: **2019-07-09, 1398/04/18**

Update count: **1**

Registration date

2018-11-27, 1397/09/06

Registrant information

Name

Farhan Mousavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 2621 6789

Email address

f.mousavi@shahed.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-22, 1397/09/01

Expected recruitment end date

2019-02-04, 1397/11/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of Holy Quran Voice on delirium prevention after cardiac surgery

Public title

The effect of Holy Quran Voice on Prevention of Delirium

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Age of 18 to above Having orientation to time, place, person Being Muslim Lack of mental disorders Talking in Farsi

Exclusion criteria:

Alcoholism or substance abuse Having a hearing problem Not having the consent to enter the study

Age

From **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Investigator
- Outcome assessor

Sample size

Target sample size: **108**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, patients will be randomly assigned to the study. By assigning the letter A to the intervention group and the letter B to the control group, the ABBA ,BABA ,ABAB ,BBAA ,AABB ,BAAB are written in separate sheets and inserted into the container. Then, we randomly take one of these sheets out of the container and write the written compound on it and replace that sheet inside the container. Since the sample size in this study is 108 patients, this procedure is repeated twenty-seven times, and each time the composition is written on each sheet in the sequence of the compound written in the previous sheet is noted. Then each of the letters of a number from one to 108 is assigned sequences written in sequence, and each of the letters is placed inside a packet and written on the envelope of that letter. Each time the patient is selected, one of these packets is opened in the order of the number written on the envelope, and it is determined that the patient should be placed in the intervention or control group.

Blinding (investigator's opinion)

Single blinded

Blinding description

The colleague of the researcher will be responsible for assigning patients to the control and intervention groups, and the researcher who has the task of evaluating the outcome will not know how to allocate patients.

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Ethics Committee for Medical Research at Shahed University

Street address

Shahed University, Tehran-Qom Express Way, Opposite Imam Khomeini's Shrine, Tehran, Iran.

City

Tehran

Province

Tehran

Postal code

3319118651

Approval date

2018-10-29, 1397/08/07

Ethics committee reference number

IR.SHAHED.REC.1397.056

Health conditions studied

1

Description of health condition studied

Delirium

ICD-10 code

F05

ICD-10 code description

Delirium due to known physiological condition

Primary outcomes

1

Description

Delirium

Timepoint

In this study, delirium is evaluated twice daily at 10 to 11 and 17 to 18 .

Method of measurement

The Confusion Assessment Method for the ICU (CAM-ICU)

Secondary outcomes

1

Description

Sleep score

Timepoint

The researcher will assess the quality and quantity once a day at 12 noon.

Method of measurement

Richard Campbell questionnaire.

2

Description

Anxiety Score

Timepoint

The level of anxiety will be evaluated on the first day of admission and on the day of discharge.

Method of measurement

Hospital Anxiety and Depression Scale (HADS)

Intervention groups

1

Description

"Intervention group": After the extubation of the patient, the voice of the Quran will be broadcast twice a day by the headphones for ten minutes.

Category

Prevention

2

Description

Control group: routine care is provided in this group.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan hospital

Full name of responsible person

Seyed Farhan Mousavi

Street address

Golestan Ave. Golestan Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahed University

Full name of responsible person

Zahra Kia Salari

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Web page address

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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

Shahed University

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

Shahed University

Full name of responsible person

Seyed Farhan Mousavi

Position

Student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

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Latest degree

Ph.D.

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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