Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 2026

The effect of non-pharmacological relaxation instructions on pain intensity, restlessness and delirium in mechanically ventilated patients after heart surgery

Protocol summary

Study aim
Design and validation of non-pharmacological relaxation instructions in patients undergoing mechanical ventilation after heart surgery Determining the effect of relaxation instructions on the incidence of delirium, pain intensity and restlessness in mechanically ventilated patients after cardiac surgery

Design
A clinical trial with control groups, with parallel groups, one-sided, randomized, will be performed on 60 patients. Randomization will be performed using a table of random numbers and card selection by samples.

Settings and conduct
A clinical trial with the content of non-pharmacological relaxation instructions, which includes music therapy reorientation and family presence, will be performed on patients who are admitted to Shahid Chamran Hospital in Isfahan for elective open heart surgery and are eligible for the study. Blinding in this study will be done only for the samples under study.

Participants/Inclusion and exclusion criteria
Perform elective open heart surgery

Intervention groups
Up to 5 hours after the patient enters the ICU-OH while the patient is under mechanical ventilation, first the reorientation message will be retrieved by the researcher based on the 5wh and 1h methods, then the music with the title of white sound taken from the sounds of nature for 30 minutes will be broadcast for the patient through headphones. After the end of the music, the patient who has received the necessary training will be present at the patient's bedside for a maximum of 30 minutes, and after the end of the intervention, the evaluations will be performed using the predicted tools.

Main outcome variables
Pain Intensity; agitation; delirium

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20130218012509N6**
Registration date: **2021-08-13, 1400/05/22**
Registration timing: **retrospective**

Last update: **2021-08-13, 1400/05/22**
Update count: **0**

Registration date
2021-08-13, 1400/05/22

Registrant information

Name
Batool Nehrir

Name of organization / entity
Baqyatallah Medical Science University

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-07-06, 1400/04/15

Expected recruitment end date
2021-08-06, 1400/05/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
The effect of non-pharmacological relaxation instructions on pain intensity, restlessness and delirium in mechanically ventilated patients after heart surgery

Public title
The effect of non-pharmacological relaxation instructions on pain intensity, restlessness and delirium in mechanically ventilated patients after heart surgery

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Ejection fraction at least 35% Surgery elective Lack of severe drug and alcohol addiction No delirium or impaired level of consciousness before surgery No severe visual or hearing impairment (blindness and deafness) Availability of first-degree family members or causal and relative relatives (at the patient's discretion) who wish to participate in the study

Exclusion criteria:
Need for long-term mechanical ventilation as directed by your doctor Need for sedation according to the doctor according to the treatment process Unpredictable events (severe bleeding, severe hemodynamic disturbance, stroke) Death of research units during the study Reluctance and consent of the patient or family to continue participating in the study

Age
From **18 years** old to **80 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization will be done in a simple way using a table of random numbers in such a way that the researcher first determines that all patients to whom the even number is assigned in group A (test) and those who become individual in group B (Control) are placed. Then close your eyes and put your finger on one of the digits in the table of random numbers and write down the house number and column number of the starting point. The direction of movement is predetermined and horizontally to the right, then It was at the top and then to the left of the table. Each even number is entered in the test group and the odd number is entered in the control group. Then all the numbers are placed in separate envelopes and all are placed in a box. When the sample with the entry conditions and easily entered the study, then the card removed from the box by the sample is opened for him and Depending on whether it has the letter A or B, the sample is placed in one of two test or control groups. In this way, sampling continues until reaching the specified sample size Found.

Blinding (investigator's opinion)
Single blinded

Blinding description
In this study, blinding will be performed for patients participating in the trial

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Baqyatallah Medical Science University

Street address
Sheikh Baha'i St. South, Baqiyatallah University of Medical Sciences

City
Tehran

Province
Tehran

Postal code
81746-73461

Approval date
2020-03-14, 1398/12/24

Ethics committee reference number
IR.BMSU.BAQ.REC.1398.051

Health conditions studied

1

Description of health condition studied
Ischemic heart disease

ICD-10 code
I25.0

ICD-10 code description
Ischemic heart disease

Primary outcomes

1

Description
Pain Intensity

Timepoint
Before and after interventions

Method of measurement
Visual Analogue Scale

2

Description
Agitation
Timepoint
Before and after interventions
Method of measurement
Richmond Agitation-Sedation Scale

3

Description
Delirium
Timepoint
Before and after interventions
Method of measurement
Confusion Assessment Method for the ICU(CAM-ICU)

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: for the intervention group, a protocol designed including: informing patients by making changes in the environment, music with the content of nature sounds and the presence of family members on the patient's bed will be used.
Category
Lifestyle

2

Description
Control group: Routine care will be provided for the control group.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Chamran Hospital
Full name of responsible person
Batul Nehrir
Street address
Salman Farsi St., Shahid Chamran Hospital
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Vice President for Research and Technology
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Sheikh Baha'i St. South, Baqiyatallah University of Medical Sciences
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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
Bagheiat-allah 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
Bagheiat-allah University of Medical Sciences
Full name of responsible person
Batul Nehrir
Position
Assistant Professor
Latest degree
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
Yes - There is a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data obtained from the study can be published after identifying the participants in the study
When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available
The data from this study will be available to researchers working in scientific and academic institutions
Under which criteria data/document could be used
There are no special conditions
From where data/document is obtainable
Contact email b.nehrir @bmsu.ac.ir
What processes are involved for a request to access data/document
Contact the email of the responsible author
Comments