

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jun 2026

The effect of playing music during surgery on postoperative pain and agitation in patients undergoing septorhinoplasty: a clinical trial

Protocol summary

Study aim

the effect of music on pain and agitation after septorhinoplasty

Design

a clinical trial with a control group, that patients have been classified as study or control by block randomization

Settings and conduct

this study will be conducted in Amir-almomenin hospital, Rasht. Patients, surgeon(before intervention), data collector and analyzer are unaware of groupings, codes are in an enclosed envelope in operation room and intervention-er has access just initiating the intervention.

Participants/Inclusion and exclusion criteria

patients 18-65 years old candidate for septorhinoplasty in amir-almomenin hospital are entered. known cases of mood disorder,known cases of hearing or cognitive problems, history of drug or alcohol abuse, history of antidepressant or tranquilizers usage, complex septorhinoplasty which requires specific techniques like harvesting conchal or costal cartilage and prolonged operation time are excluded

Intervention groups

music will be played in study group in earphones, control group will hear silence

Main outcome variables

pain , agitation after surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210307050609N2**

Registration date: **2022-04-11, 1401/01/22**

Registration timing: **registered_while_recruiting**

Last update: **2022-04-11, 1401/01/22**

Update count: **0**

Registration date

2022-04-11, 1401/01/22

Registrant information

Name

Sevil Nasirmohtaram

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3323 8307

Email address

sevil198@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-06, 1400/12/15

Expected recruitment end date

2022-06-21, 1401/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of playing music during surgery on postoperative pain and agitation in patients undergoing septorhinoplasty: a clinical trial

Public title

The effect of music on pain and agitation after septorhinoplasty

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

candidates of septorhinoplasty

Exclusion criteria:

known cases of mood disorder known cases of hearing or cognitive problems history of drug or alcohol abuse history of antidepressant or tranquilizers usage complex septorhinoplasty which requires specific techniques like harvesting conchal or costal cartilage and prolonged operation time

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization will be performed in 25 blocks of four, via sealed envelope software in www.sealedenvelope.com. A unique randomization code will be devoted to each randomization number group, the codes are recorded in questionnaires. the interventioner will play file 1 or 2 of playlist based on the matched code list in operating room, while unaware of playlist.

Blinding (investigator's opinion)

Double blinded

Blinding description

At the time of history taking , a coded checklist will be put in patients records. Decoding is inaccessible for everyone except for intervention-er. the intervention-er who is in operation room is not in touch with patient and wont see the code before entrance of patient to operation theater. All the checklists are gathered by residents who are unaware of codes and grouping. List of codes are kept in an envelope in a locked case in operation room, lock is kept by secretary. The surgeon, surgical technician, and patients are unaware of groups before beginning of intervention. Surgical technician, anesthesiologist and anesthesiology technician are unaware of music played in earphones. During induction the resident will play playlist 1 (music) or 2(silence), based on the code. surgical aid circular will record operation time, pulse rate and mean arterial pressure. Anesthesiologist colleague will record agitation-sedation score. Patient satisfaction will be recorded in ward by a resident.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Gilan University of medical sciences

Street address

Amir-almomenin hospital, 17 shahrivar Ave.

City

Rasht

Province

Guilan

Postal code

4165755199

Approval date

2022-02-04, 1400/11/15

Ethics committee reference number

IR.GUMS.REC.1400.538

Health conditions studied

1

Description of health condition studied

pain and agitation after surgery

ICD-10 code

F-41

ICD-10 code description

other anxiety disorders

Primary outcomes

1

Description

agitation after surgery

Timepoint

evaluation of agitation during extubation and in recovery ward

Method of measurement

with sedation-agitation score

2

Description

pain after surgery

Timepoint

in recovery ward

Method of measurement

with visual analogue scale

Secondary outcomes

1

Description

patient satisfaction of operation process

Timepoint

once in ward

Method of measurement

checklist based on patient's declare

Intervention groups**1****Description**

Intervention group: music played via earphone during surgery. In study group instrumental music (piano played by master Javad Maroofi, with a mean rhythm of 80 bytes per minute and with a intensity of 50-65 dB) will be played from induction phase till the end of the operation.

Category

Treatment - Other

2**Description**

Control group: silence played via earphones during surgery

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Amir-almomenin hospital

Full name of responsible person

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

Sevil Nasirmohtaram

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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

Rasht 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**

Rasht University of Medical Sciences

Full name of responsible person

Sevil Nasirmohtaram

Position

assisstant professor

Latest degree

Specialist

Other areas of specialty/work

Ear, Nose, and Throat

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

Sevil Nasirohtaram

Position

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Latest degree

Specialist

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 can be shared after omitting personal information

When the data will become available and for how long

after submitting the article

To whom data/document is available

researchers in academic fields

Under which criteria data/document could be used

just as a reference for their own studies

From where data/document is obtainable

email to cor-responder

What processes are involved for a request to access data/document

sending an email, receiving the data after evaluating the request

Comments**Person responsible for updating data****Contact****Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

Sevil Nasirmohtaram

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Ear, Nose, and Throat

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