Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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)
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+98 13 3323 8307
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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 secretory. 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 declaire

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
Sevil Nasirmohtaram
Street address
No.17 , 108 Ave.,Golsar Blvd
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Rasht 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
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 updating data

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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