Clinical Trial Protocol
Iranian Registry of Clinical Trials

02 Aug 2026

The effect of familiar voice auditory stimulation on anesthesia recovery among patients under gone to rhinoplasty

Protocol summary

Study aim
Determination of the effect of familiar voice auditory stimulation on anesthesia recovery among patients under gone to rhinoplasty

Design
A randomized, single-blind, placebo-controlled clinical trial with a sample size of eighty

Settings and conduct
One-blind clinical trial in patients undergoing rhinoplasty in the recovery ward with the same anesthesia protocol, complete randomization to the intervention and control groups. In the intervention group despite receiving routine nursing care in recovery, they receive a stimulation of the auditory sensation that captures the recorded voice of the individual accompanying the patient for an average of three minutes continuously for fifteen minutes in the recovery unit using the MP3 player via headphones. The second group as the control group, despite having headphones in the ear, does not receive any audio from the headphones and receive only routine nursing care.

Participants/Inclusion and exclusion criteria
Inclusion criteria included patients undergoing rhinoplasty, obtaining informed consent from the patient and their family, age range 18 to 60 years, no history of hearing impairment, patients being classified as Class 1 Physical Examination by the American Society of Experts; Exclusion criteria included body mass index more than thirty-five and less than eighteen and a half, mental illness, drug and psychiatric disorders, heart, lung, kidney and liver disease.

Intervention groups
In the intervention group, in spite of receiving routine nursing care, they receive auditory stimulation, which is the recorded voice of the individual accompanying the patient with the specified content, in the postoperative recovery unit through the headphones and the control group only receive routine nursing care and no audio from their headphones.

Main outcome variables
Duration of anesthesia recovery; hemodynamic status; complications of anesthesia

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190707044129N1**
Registration date: **2019-12-29, 1398/10/08**
Registration timing: **registered_while_recruiting**

Last update: **2019-12-29, 1398/10/08**
Update count: **0**

Registration date
2019-12-29, 1398/10/08

Registrant information

Name
Shamsaldin Mohammadi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 3336 1577

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shamsodin.mohammadi1396@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-12-29, 1398/10/08

Expected recruitment end date
2020-03-30, 1399/01/11

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of familiar voice auditory stimulation on anesthesia recovery among patients under gone to rhinoplasty

Public title

The effect of auditory stimulation on anesthesia recovery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Patients are candidates for rhinoplasty Patients are classified in class 1 in the classification of the physical condition of the American Society of Anesthesiologists Patients are between the ages of 18 and 60 years Getting informed consent from the patient and his or her family Patients with no history of hearing impairment

Exclusion criteria:

Body mass index is more than thirty five and less than eighteen and a half The presence of mental illness Drug Addiction and Psychoanalysis Heart disease, lung, kidney, liver disease

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **80**

Randomization (investigator's opinion)

Randomized

Randomization description

In order to randomize the study, simple randomization with individual unit is used, so that patients are randomly assigned to two intervention and control groups using random numbers.

Blinding (investigator's opinion)

Single blinded

Blinding description

Before the surgery and after consultation with the patient regarding the choice of the accompanying the patient and the informed consent of the patient and his or her family, the recorded voice accompanying the patient to stimulate the postoperative auditory hearing is used in recovery in the intervention group, But the patient is unaware of being in the intervention or control group

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Yazd University of Medical Sciences

Street address

School of Public Health, Shahid Sadoughi University of Medical Sciences, Shohadaye Gomnam Blvd., Alem Square, Yazd, Iran

City

Yazd

Province

Yazd

Postal code

8915173160

Approval date

2019-07-29, 1398/05/07

Ethics committee reference number

IR.SSU.SPH.REC.1398.047

Health conditions studied

1

Description of health condition studied

Anesthesia recovery

ICD-10 code

T88.59

ICD-10 code description

Other complications of anesthesia

Primary outcomes

1

Description

Average of anesthesia recovery time

Timepoint

Since the removal of the endotracheal tract to a score of 9 out of 10

Method of measurement

A valid and standard Aldert Score checklist

Secondary outcomes

1

Description

Hemodynamic status

Timepoint

Before anesthesia, before the auditory stimulation, 5, 10 and 15 minutes after the auditory stimulation, the discharge time of recovery

Method of measurement

Monitoring device

2

Description
Complications of anesthesia
Timepoint
Since the removal of the endotracheal tract until recovery ward discharge
Method of measurement
Check list

Intervention groups

1

Description
Intervention group: In addition to receiving routine nursing care in recovery, the auditory stimulation is performed in a continuous recovery unit with a patient's accompanying and patient's consultation, and an average of 3 minutes, for 15 minutes. The use of MP3 player and headphones with sound intensity in the normal range of hearing is 50 to 60 db
Category
Prevention

2

Description
Control group: This group only receives routine nursing care in recovery, but despite having headphones, no sound will be delivered to them.
Category
N/A

Recruitment centers

1

Recruitment center
Name of recruitment center
Injuries and burns hospital
Full name of responsible person
Mohamadhosein Dehghani
Street address
Injuries and burns hospital, Shaheed Paknezhad Boulevard, Moallem Square
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Masoud Mirzaei
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Shahid Sadoughi University of Medical Sciences Yazd., Bahonar Square
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Yazd
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8916978477
Phone
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Fax
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Email
mirzaeim@med.usyd.edu.au
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yazd 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
Yazd University of Medical Sciences
Full name of responsible person
Shamsodin Mohammadi
Position
Student
Latest degree
Master
Other areas of specialty/work
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Person responsible for scientific inquiries

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Position

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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

No - There is not 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

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available

Title and more details about the data/document

Information about the main outcome can be shared.

When the data will become available and for how long

Start the access period 3 months after publishing the results

To whom data/document is available

Researchers working in academia

Under which criteria data/document could be used

Use data to complete clinical trial studies

From where data/document is obtainable

Esfahan Ayatollah Kashani Hospital

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

After the investigation of researcher request and presentation of required documents will be accessible.

Comments