Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Jul 2026

Investigating the preventive effect of dexmedetomidine infusion on recovery indicators after rhinoplasty surgery under general anesthesia

Protocol summary

Study aim
Determining and comparing the preventive effect of dexmedetomidine infusion on recovery indicators after rhinoplasty under general anesthesia

Design
A randomized, triple-blinding clinical trial, with the parallel groups, Phase 3 on 60 patients

Settings and conduct
In this randomized three-blind randomized clinical trial, 60 eligible patients referred to Al-Zahra Hospital in Isfahan will be included in the study and randomly divided into 3 groups. Before the end of surgery, patients are prescribed different doses of dexmedetomidine or normal saline by two methods, bolus and infusion.Then the intensity of pain and chills of the patients will be evaluated and compared among the three groups.

Participants/Inclusion and exclusion criteria
The inclusion criteria include the age group of 18 to 65 years, candidate for rhinoplasty surgery under general anesthesia, class I and II of the American Society of Anesthesiology(ASA), and consent to participate in the study. Exclusion criteria include addiction, history of previous allergy to dexmedetomidine, body mass index (BMI) above 30 kg/m2, and taking painkillers or neuropsychiatric drugs before the intervention.

Intervention groups
The first intervention group: Half an hour before the end of the surgery, dexmedetomidine 1 microgram/kg bolus dose will be prescribed within 10 minutes, and then half microgram/kg infusion and continue until 30 minutes after recovery. The second intervention group: Half an hour before the end of the surgery, 1 microgram/kg bolus dose will be prescribed within 10 minutes, then 0.7 microgram/kg infusion and continue until 30 minutes after entering recovery. Control group: half an hour before the end of the surgery, normal saline will be administered in the same volume as the intervention groups in the form of bolus and infusion.

Main outcome variables
Pain; Chills; Restlessness; Nausea; Vomiting

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200825048515N57**
Registration date: **2022-08-28, 1401/06/06**
Registration timing: **registered_while_recruiting**

Last update: **2022-08-28, 1401/06/06**
Update count: **0**

Registration date
2022-08-28, 1401/06/06

Registrant information

Name
Asieh Maghami Mehr

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 31 0000 0000

Email address
asimaghami@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-08-23, 1401/06/01

Expected recruitment end date
2023-03-22, 1402/01/02

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Investigating the preventive effect of dexmedetomidine infusion on recovery indicators after rhinoplasty surgery under general anesthesia

Public title
Investigating the effect of dexmedetomidine on recovery indicators after rhinoplasty surgery

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age range18 to 65 years Rhinoplasty surgery candidate under general anesthesia American Society of Anesthesiology (ASA) class one and two Consent to participate in the study

Exclusion criteria:
Addiction The history of previous allergy to dexmedetomidine body mass index (BMI) above 30 kg/m2 Taking painkillers or neuropsychiatric drugs before the intervention

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
In this study, 60 eligible patients are randomly selected. Then the letters A, B and C are written on 20 sheets and each one is placed in an envelope. Each patient is then asked to choose one of the envelopes. Depending on the selected envelope, the patient is assigned to one of three groups.

Blinding (investigator's opinion)
Triple blinded

Blinding description
In order to achieve the triple-blind study, different doses of Dexmedetomidine and placebo will be prepared daily by the operating room nurse (without the researcher's awareness) and placed in the bag and will be labeled A, B, C, and D. And is given daily to the anesthesiologist (researcher). Therefore, the patient, the Investigator, the person recording the clinical and basic information of the patients as well as the statistical analyst will not be aware of the type of intervention.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences

Street address
Street address Isfahan University of Medical Sciences, Hezar Jarib Ave., Azadi Sq

City
Isfahan

Province
Isfehan

Postal code
8179964167

Approval date
2022-07-22, 1401/04/31

Ethics committee reference number
IR.MUI.MED.REC.1401.166

Health conditions studied

1

Description of health condition studied
Rhinoplasty

ICD-10 code
J34

ICD-10 code description
Other and unspecified disorders of nose and nasal sinuses

Primary outcomes

1

Description
Pain

Timepoint
Immediately after entering recovery and then every 15 minutes until leaving recovery

Method of measurement
Visual Analogue Scale

2

Description
Chilling

Timepoint
Immediately after entering recovery and then every 15 minutes until leaving recovery

Method of measurement

Based on the shivering criterion (0: no shivering / 1: weak fasciculation of face and neck muscles / 2: visible tremor in more than one muscle group)

3

Description
Restlessness
Timepoint
Immediately after entering recovery and then every 15 minutes until leaving recovery
Method of measurement
Riker sedation-agitation scale

Secondary outcomes

1

Description
Nausea
Timepoint
Immediately after entering recovery and then every 15 minutes until leaving recovery
Method of measurement
0: not having nausea, 1: mild nausea, 2: moderate nausea, and 3: sever nausea

2

Description
Vomiting
Timepoint
Immediately after entering recovery and then every 15 minutes until leaving recovery
Method of measurement
0: no vomiting, 1: little vomiting, 2: vomiting gastric contents, and 3: vomiting of food particles.

Intervention groups

1

Description
Control group: half an hour before the end of the surgery, normal saline will be administered in the same volume as the intervention groups in the form of bolus and infusion.
Category
Placebo

2

Description
The first intervention group: Half an hour before the end of the surgery, dexmedetomidine 1 microgram/kg bolus dose will be prescribed within 10 minutes, and then half microgram/kg infusion and continue until 30 minutes after recovery.
Category
Treatment - Drugs

3

Description
The second intervention group: Half an hour before the end of the surgery, 1 microgram/kg bolus dose will be prescribed within 10 minutes, then 0.7 microgram/kg infusion and continue until 30 minutes after entering recovery.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra Hospital
Full name of responsible person
Azim Honarmand
Street address
Anesthesiology Department, Al-Zahra Hospita, Sefeh Blvd., Tohid Street
City
Isfahan
Province
Isfehan
Postal code
8174675731
Phone
+98 31 3620 2020
Email
honarmand@med.mui.a.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Mansour Siavash Dastjerdi
Street address
Vice Chancellor for Research, School of Medicine, Hezar Jarib Street, Isfahan.
City
Isfahan
Province
Isfehan
Postal code
8174673461
Phone
+98 31 3668 8597
Email
dean@med.mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
No
Title of funding source

Isfahan University of Medical Sciences

Proportion provided by this source
100

Public or private sector
Private

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
Esfahan University of Medical Sciences

Full name of responsible person
Azim Honarmand

Position
Professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

Street address
Anesthesiology Department, Al-Zahra Hospita, Sefeh Blvd., Tohid Street

City
Isfahan

Province
Isfehan

Postal code
8174675731

Phone
+98 31 3620 2020

Email
honarmand@med.mui.a.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Azim Honarmand

Position
Professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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City
Isfahan

Province
Isfehan

Postal code
8174675731

Phone
+98 31 3620 2020

Email
honarmand@med.mui.a.ir

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Fatemeh Mohrezi Nejad

Position
General practitioner

Latest degree
Medical doctor

Other areas of specialty/work
Anesthesiology

Street address
Anesthesiology Department, Al-Zahra Hospita, Sefeh Blvd., Tohid Street

City
Isfahan

Province
Isfehan

Postal code
8174675731

Phone
+98 31 3620 2020

Email
fmhrzy@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no further information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not 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