

Clinical Trial Protocol

Iranian Registry of Clinical Trials

23 Jul 2026

Comparison of the Effect of Dexmedetomidine, Remifentanyl and Metoral on Reducing Bleeding and Surgery Satisfaction During Rhinoplasty

Protocol summary

Study aim

Determination of the effect of Dexmedetomidine, Remifentanyl and Metoral on reducing patient's hemorrhage and surgery satisfaction during rhinoplasty

Design

This study is a double-blind randomized clinical trial of patients undergoing rhinoplasty candidate. After the anesthetic induction, the patients were placed under the ventilator and ready for rhinoplasty. Subsequently, for the patients in the first group, 0.5 mg / kg / h dose of dexmedetomidine in the second group, 50-100 µm / kg / hr Fentanyl and in the third group, 50 mg Metoral will be infused.

Settings and conduct

This study is a double-blind randomized clinical trial of patients undergoing rhinoplasty candidate referring to Amirkabir Hospital in Arak. After the anesthetic induction, the patients were placed under the ventilator and ready for rhinoplasty. Subsequently, for the patients in the first group, 0.5 mg / kg / h dose of dexmedetomidine in the second group, 50-100 µm / kg / hr Fentanyl and in the third group, 50 mg Metoral will be infused.

Participants/Inclusion and exclusion criteria

Entry: All patients with rhinoplasty candidates referring to Amir Kabir Hospital, patients aged 18 to 50 years and all patients undergoing surgery by a surgeon. No entry: Patients who have a cardiogenic disorder during operation or even have a heart arrest A respiratory arrest has occurred to them

Intervention groups

Subsequently, for the patients in the first group, 0.5 mg / kg / h dose of dexmedetomidine in the second group, 50-100 µm / kg / hr Fentanyl and in the third group, 50 mg Metoral will be infused.

Main outcome variables

For all of the patients in the three groups, a questionnaire including demographic information, as well as data on MAP, PR, mean score of bleeding, controlled

hypotension, and the rate of rhythm and morbidity and mortality were completed.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180903040936N2**

Registration date: **2019-09-02, 1398/06/11**

Registration timing: **registered_while_recruiting**

Last update: **2019-09-02, 1398/06/11**

Update count: **0**

Registration date

2019-09-02, 1398/06/11

Registrant information

Name

Narges Anousheh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4449 7630

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nargesanousheh1994@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-08-15, 1398/05/24

Expected recruitment end date

2019-12-15, 1398/09/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effect of Dexmedetomidine, Remifentanyl and Metoral on Reducing Bleeding and Surgery Satisfaction During Rhinoplasty

Public title

Comparison of the Effect of Dexmedetomidine, Remifentanyl and Metoral on Reducing Bleeding and Surgery Satisfaction During Rhinoplasty

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

All patients with Rhinoplasty who referred to Amir Kabir Hospital in Arak Patients aged 18 to 50 years

Exclusion criteria:

Patients who have had a specific heart attack or even a heart attack during the operation Patients who are unable to get metroral due to early bradycardia.

Age

From **18 years** old to **50 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: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

This study is a double-blind randomized clinical trial of patients undergoing rhinoplasty in the Amir Kabir hospital of Arak. A sample of 75 patients with a candidate rhinoplasty that has been studied by a cardiologist and selected by a cardiologist is selected and divided into three randomly assigned randomized complete sets randomly divided into three groups: Remifentanyl, Metoral, and Dexmedetomidine.

Blinding (investigator's opinion)

Double blinded

Blinding description

The drugs required for infusion are prepared for anesthetist by the anesthetist and in each of the 3 groups 50 cc syringes are provided with a similar appearance to the partner in order to provide infusion to the patients. also intern responsible for the plan who is responsible for completing the questionnaire, is not aware of the type of study group. Syringes containing infusion solutions are placed on the A, B, and C adhesives for the patients, provided with a syringe A, B and C.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Arak University of Medical Sciences

Street address

Arak University of Medical Sciences,next to Amiralmomenin Hospital, Basij Square,Sardasht

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2019-05-05, 1398/02/15

Ethics committee reference number

IR.ARAKMU.REC.1398.39

Health conditions studied**1****Description of health condition studied**

Comparison of the Effect of Dexmedetomidine, Remifentanyl and Metoral on Reducing Bleeding and Surgery Satisfaction During Rhinoplasty

ICD-10 code

I95.2:

ICD-10 code description

Hypotension due to drugs

Primary outcomes**1****Description**

Average MAP of patients

Timepoint

Immediately, 5 minutes, 15 minutes, 30 minutes, 45 minutes, 60 minutes, 75 minutes, 90 minutes and 2 hours after anesthesia.

Method of measurement

Mercury and digital pressure gauge device

2**Description**

Average heart rate of patients

Timepoint

Immediately, 5 minutes, 15 minutes, 30 minutes, 45 minutes, 60 minutes, 75 minutes, 90 minutes and 2 hours after anesthesia.

Method of measurement

Cardiac monitoring

3**Description**

Average scour of bleeding during surgery

Timepoint

During surgery

Method of measurement

By check list and according to the amount of gas used to prevent bleeding

4**Description**

Surgeon Satisfaction

Timepoint

After the completion of surgery

Method of measurement

Based on checklist

Secondary outcomes

empty

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

Intervention group: After the anesthetic induction, the patients are examined and placed under the ventilator, then they are done and ready for rhinoplasty. Then, for patients in the first group, 0.5 mg / kg / h will be dosed as Dexmedetomidin infusion.

Category

Treatment - Drugs

2**Description**

Intervention group: Intervention group: After the anesthetic induction, the patients are examined and placed under the ventilator, then they are done and ready for rhinoplasty. Then, for patients in the first group, 50-100µ / kg / h will be dosed as Remifentanyl infusion

Category

Treatment - Drugs

3**Description**

Intervention group: Intervention group: After the anesthetic induction, the patients are examined and placed under the ventilator, then they are done and ready for rhinoplasty. Then, for patients in the first group, 50 mg will be dosed as Metoral infusion.

Category

Treatment - Drugs

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

Amir Kabir Hospital in Arak

Full name of responsible person

Narges Anousheh

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Shahid Shirodi street - Nursing square

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

Arak University of Medical Sciences

Full name of responsible person

Alireza Kamali

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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

Arak 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

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

Arak University of Medical Sciences

Full name of responsible person

Narges Anousheh

Position

Medical Student

Latest degree

A Level or less

Other areas of specialty/work

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Phone**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

Undecided - It is not yet known if there will be 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

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available