Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

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

Protocol summary

Study aim

Determination of the effect of Dexmedetomidine, Remifentanil 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 Fentanil 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 Fentanil 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 entery: 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 Fentanil 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

Email address

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, Remifentanil and Metoral on Reducing Bleeding and Surgery Satisfaction During Rhinoplasty

Public title
Comparison of the Effect of Dexmedetomidine, Remifentanil 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: Remifentanil, 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, Remifentanil 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 Remifentanil 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
Street address
Shahid Shirodi street - Nursing square
City
Arak
Province
Markazi
Postal code
3848176941
Phone
+98 86 3313 4715
Email
Rsearch@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Alireza Kamali
Street address
Basij Square , Arak University of Medical Sciences
City
Arak
Province
Markazi
Postal code
3848176941
Phone
+98 86 3417 3645
Email
Rsearch@arakmu.ac.ir
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

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
Anesthesiology
Street address
Ashrafi Esfahani Highway
City
Tehran
Province
Tehran
Postal code
1476985574
Phone
+98 21444976300
Email
www.nargesanousheh1994@gmail.com

Person responsible for scientific 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
Anesthesiology
Street address
Ashrafi Esfahani Highway
City
Tehran
Province
Tehran
Postal code
1476985574
Phone
+98 21444976300
Email
www.nargesanousheh1994@gmail.com

Person responsible for updating data

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
Anesthesiology
Street address
Ashrafi Esfahani Highway
City
Tehran
Province
Tehran
Postal code
1476985574
Phone
+98 21444976300
Email
www.nargesanousheh1994@gmail.com

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