Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Sep 2026

Comparing the effect of Dexmedetomidine and Remifentanil of induce controlled hypotension during rhinoplasty

Protocol summary

Study aim
Comparison of the effect of Dexmedetomidine and Remifentanil on controlling hypotension during rhinoplasty

Design
This study is clinical trial and double blind.60 patients candidate rhinoplasty in Amirkabir Hospital in Arak will be entered in this study. We will divide patients in 2 groups by simple randomization.Groups are parallel.

Settings and conduct
This study is clinical trial and double blind. 60 patients candidate for rhinoplasty in Amirkabir Hospital in Arak will be entered in this study. Outcome assessor and analyzer and participants will not be aware from grouping.

Participants/Inclusion and exclusion criteria
Inclusion criteria:all patients with rhinoplasty referring to Amir Kabir Hospital in Arak, patients aged 18 to 50 years, patients with ASA Class I and II, all patients undergo surgery by one surgeon, the operating time is between 90 to 180 minutes Exclusion criteria:patients with ASA Classes 3 and 4 , patients who have allergies to dexmedetomidine or remifentanil

Intervention groups
For patients in first group , we will infuse 0.5 micro grams per kilogram in 1 hour Dexmedetomidine and for the second group, infuse 50-100 micro grams per kilogram in 1 hour of Remifentanil.

Main outcome variables
Mean of blood pressure, mean of pulse rate, mean of bleeding score, mean recovery time

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190410043231N1**
Registration date: **2019-07-13, 1398/04/22**
Registration timing: **retrospective**

Last update: **2019-07-13, 1398/04/22**
Update count: **0**

Registration date
2019-07-13, 1398/04/22

Registrant information

Name
Farzane Farmani

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 25 3882 6802

Email address
f.farmani@arakmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2019-04-27, 1398/02/07

Expected recruitment end date
2019-06-28, 1398/04/07

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparing the effect of Dexmedetomidine and Remifentanil of induce controlled hypotension during rhinoplasty

Public title
Comparing the effect of Dexmedetomidine and Remifentanil for induction of controlled hypotension

during rhinoplasty

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All patients with rhinoplasty referring to Amir Kabir Hospital in Arak Patients aged 18 to 50 years Patients with ASA class I and II All patients undergo surgery by a surgeon Operating time is between 90 to 180 minutes

Exclusion criteria:

Patients outside the age range of 18 to 50 years Patients with ASA classes 3 and 4 Patients who have allergies to Dexmedetomidine or Remifentanil

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

1-2

Groups that have been masked

- Participant
- Care provider
- Investigator

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple individual randomization with envelopes in three groups A and B and C. In this method, some cards will be signed as intervention group1 and the same number of cards for intervention group 2 and the same number of cards for the control group, then the cards will be mixed. One card will be taken out and its group name will be registered and then card will be returned to the container again. Then the cards will be mixed again and another card will be taken. This process will be continued to reach a random sequence according to sample size.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double blind. Researcher who complete questionnaire and analyzer and participant will be blind (double blind). Outcome assessor and analyzer and participants will not be aware from grouping.The person evaluating the outcome will be unaware of the grouping. Definition of groups A and B will be available to analyzer and outcome assessor.

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

Ethics comittee, Research center, Payambar Azam complex, Basij Squre ,Sardasht,Arak

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2018-08-19, 1397/05/28

Ethics committee reference number

IR.ARAKMU.REC.1397.137

Health conditions studied

1

Description of health condition studied

Rhinoplasty

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Mean arterial pressure

Timepoint

At 15, 30, 45, 60, 90, and 120 minutes after the start of operation

Method of measurement

Barometer

2

Description

Mean of pulse rate

Timepoint

At 15, 30, 45, 60, 90, and 120 minutes after the start of operation

Method of measurement

Pulse rate counts

3

Description

Mean of recovery time

Timepoint

Recovery

Method of measurement

Record time in recovery book

4

Description

Mean of bleeding score

Timepoint

At 15, 30, 45, 60, 90, and 120 minutes after the start of operation

Method of measurement

Suction and observation of blood gas

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Dexmedetomidine, 0.5 micro grams per kilogram per hour for infusion during surgery

Category

Treatment - Drugs

2

Description

Intervention group 2: Remifentanil 50 to100 micro grams per kilogram per hour for infusion during surgery

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amirkabir hospital

Full name of responsible person

Farzane Farmani

Street address

Amirkabir hospital, Parastar square, Shahidshirodi St, Arak

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Mohammad Arjmandzadegan

Street address

Research Center, Payambar Azam Complex, Basij square, Sardasht, Arak

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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

Person responsible for general inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Alireza Kamali

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific

inquiries

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Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Anesthesiology

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Person responsible for updating data

Contact

Name of organization / entity
Arak University of Medical Sciences

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Medicine student

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A Level or less

Other areas of specialty/work
General Practitioner

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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
When we publish article in journal

When the data will become available and for how long
After the article is published

To whom data/document is available
Researchers working in academic and scientific institutions

Under which criteria data/document could be used
If there are additional questions

From where data/document is obtainable
Person responsible for the accountability of Dr. Alireza Kamali alikamaliir@yahoo.com

What processes are involved for a request to access data/document
Send an e-mail containing the layout specifications to the person responsible for the scientific answer

Comments