

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

Comparison of the effect of labetalol and dexmedetomidine in induction of control hypotension in patients with rhinoplasty

Protocol summary

Study aim

Comparison effect of labetalol and dexmedetomidine for controlled hypotension in patients with rhinoplasty

Design

The study will be double blind and clinical trial. 64 patients will be randomly divided into 2 groups. The groups are parallel. The trial phase is 3.

Settings and conduct

Patients candidate for rhinoplasty in Amirkabir Hospital in Arak are divided into 2 groups by simple randomization with block. The study is double-blind in which outcome evaluator and data analyst and participant are kept blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age range 18 to 45 years, body mass index 20 to 30, no history of cardiovascular disease, pulmonary disease, renal disease and hepatic diseases, no history of allergy to labetalol and dexmedetomidine, no pregnancy and lactation, ASA class I and II Exclusion criteria: For any reason, they have suffered cardiorespiratory arrest during previous surgeries

Intervention groups

The first group of intervention: We will infuse 0.3 milligram in kilogram in hours of labetalol during surgery. The second group of intervention: We will infuse 0.5 microgram in kilogram in hours Dexmedetomidine during surgery.

Main outcome variables

Sedation, bleeding

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141209020258N171**

Registration date: **2022-01-16, 1400/10/26**

Registration timing: **registered_while_recruiting**

Last update: **2022-01-16, 1400/10/26**

Update count: **0**

Registration date

2022-01-16, 1400/10/26

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-01-05, 1400/10/15

Expected recruitment end date

2023-01-05, 1401/10/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of labetalol and dexmedetomidine in induction of control hypotension in patients with rhinoplasty

Public title

Comparison of the effect of labetalol and dexmedetomidine in induction of control hypotension in patients with rhinoplasty

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age range 18 to 45 years Candidate patients for rhinoplasty surgery Body mass index 20 to 30 The duration of surgery is between 90 to 150 minutes No history of cardiovascular disease, pulmonary disease, renal disease and hepatic diseases No history of allergy to labetalol and dexmedetomidine No pregnancy and lactation ASA class I and II

Exclusion criteria:
For any reason, they have suffered cardiorespiratory arrest during previous surgeries

Age
From **18 years** old to **45 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **64**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be allocated into 2 groups using a permuted balanced block randomization method with the size of blocks 4 and 8. Random sequence will be generated by an epidemiologist by running an online program in sealed envelope website (<https://www.sealedenvelope.com/>). Random chain concealment is done by opaque envelope method.

Blinding (investigator's opinion)
Double blinded

Blinding description
It is a double-blind study. Analysts, evaluators, and participants are unaware of the grouping. The intern is unaware of the drugs prescribed in each group and the anesthesiologist prepares the drugs and provides them to the intern, and the patients are not aware of their group.

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 committee, Research center, Payambar Azam complex, Basij square, Sardasht, Arak

City
Arak

Province
Markazi

Postal code
3848176941

Approval date
2021-11-17, 1400/08/26

Ethics committee reference number
IR.ARAKMU.REC.1400.239

Health conditions studied

1

Description of health condition studied

Rhinoplasty

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Sedation

Timepoint

Recovery

Method of measurement

Ramsay score

2

Description

Bleeding

Timepoint

During operation and recovery

Method of measurement

Observation, The amount of bleeding is reported on millilitre.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: We will infuse 0.3 milligram in kilogram in hours of labetalol during surgery.

Category

Treatment - Drugs

2

Description

Intervention group 2: We will infuse Dexmedetomidine 0.5 microgeram in kilogram in hours during surgery.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Amirkabir hospital

Full name of responsible person

Dr HALireza Kamali

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Sponsors / Funding sources

1

Sponsor

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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

Dr Behnam Mahmodie

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for updating data

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Fax

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