

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparing sublingual nitroglycerine vs. combination of sublingual nitroglycerine and intravenous neostigmine on inducing hypotension on patients undergoing rhinoplasty in bouali hospital of Tehran 2019

Protocol summary

Study aim

Comparing sublingual nitroglycerine vs. combination of sublingual nitroglycerine and intravenous neostigmine on inducing hypotension on patients undergoing rhinoplasty based on age, sex, operation duration, heart rate, and blood pressure.

Design

Randomized clinical trial, two-arm parallel, three-way blinded, with the controlled group

Settings and conduct

Patients are categorized into A and B group by anesthesiologist using random number table(researcher and patients are blinded). One group receives drug while the other group receives placebo. Data noted by the researcher is given to data analyzer who is blinded also.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Elective rhinoplasty Age between 15-60 ASA class I and II No addiction Not included in the study: Not pleased to be part of the study History of any drug reaction Age less than 15 or more than 60 ASA class III or more addiction

Intervention groups

All the patients received a puff of sublingual Nitroglycerin per each 50 kg of weight. One group receives 0.3 mg/kg of IV placebo and the other group receives 0.3 mg/kg IV Neostigmine(researcher is blinded). Inducing anesthesia is by 3 ug/kg Fentanyl, 0.1-0.2 mg/kg Midazolam, 5 mg/kg Nesdonal and 0.5 mg/kg Atracirium. Maintaining anesthesia is by infusion of 1 ug/kg Fentanyl, 0.1 mg/kg Atracirium and 6-12 mg/kg/h Propofol.

Main outcome variables

Blood pressure; heart rate; surgery duration

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20151201025321N1**

Registration date: **2019-09-07, 1398/06/16**

Registration timing: **retrospective**

Last update: **2019-09-07, 1398/06/16**

Update count: **0**

Registration date

2019-09-07, 1398/06/16

Registrant information

Name

Amirnezam Mir

Name of organization / entity

IAUM , MEDICAL SHCOOL

Country

Iran (Islamic Republic of)

Phone

+98 51 3729 2920

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-22, 1397/10/01

Expected recruitment end date

2019-06-22, 1398/04/01

Actual recruitment start date

2019-03-05, 1397/12/14

Actual recruitment end date

2019-07-06, 1398/04/15

Trial completion date

2019-07-07, 1398/04/16

Scientific title

Comparing sublingual nitroglycerine vs. combination of sublingual nitroglycerine and intravenous neostigmine on inducing hypotension on patients undergoing rhinoplasty in bouali hospital of Tehran 2019

Public title

Induced hypotension in rhinoplasty

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

elective rhinoplasty ASA class I & II No addiction age between 15 to 60

Exclusion criteria:

patient not pleased to participate in study drug reaction history ASA class III or more Addiction

Age

From **15 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Actual sample size reached: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

First, we designed a 10*6 table of random numbers including numbers from 01 to 60. The researcher will give each patient a number from the top of the list, the next patient will receive the bottom number and so on. patients with even numbers will receive A intervention and patients with odd numbers will receive B intervention.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Patients don't know which drug is used for them. The surgeon who surveys the consequence of using the drug doesn't know which drug is used for the patient. Data analyzer don't know which drug is used for the patient. Researcher don't know which drug is used for the patient.

Placebo

Used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

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12 Unit, NO 28, W. Kavian, Haghani highway

City

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Postal code

1541737175

Approval date

2019-03-04, 1397/12/13

Ethics committee reference number

IR.IAU.TMU.REC.1398.056

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

Induced hypotension

ICD-10 code

I95.2

ICD-10 code description

Hypotension due to drugs

2**Description of health condition studied**

Rhinoplasty

ICD-10 code

Z41.1

ICD-10 code description

Encounter for cosmetic surgery - rhinoplasty

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

Blood pressure

Timepoint

Every 5 minute in first hour and every 15 minute in next hours

Method of measurement

Sphygmomanometer

2**Description**

Heart rate

Timepoint

Every 5 minute in first hour and every 15 minute in next hours

Method of measurement

Cardiac monitoring screen

3

Description

Operation duration

Timepoint

At the end of the operation

Method of measurement

Digital chronometer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This group receives 0.3 mg/kg IV Neostigmine(researcher is blinded). Inducing anesthesia is by 3 ug/kg Fentanyl,0.1-0.2 mg/kg Midazolam, 5 mg/kg Nesdonal and 0.5 mg/kg Atracirium. Maintaining anesthesia is by infusion of 1 ug/kg Fentanyl, 0.1 mg/kg Atracirium and 6-12 mg/kg/h Propofol.

Category

Prevention

2

Description

Control group: This group receives 0.3 mg/kg of IV placebo. Inducing anesthesia is by 3 ug/kg Fentanyl,0.1-0.2 mg/kg Midazolam, 5 mg/kg Nesdonal and 0.5 mg/kg Atracirium. Maintaining anesthesia is by infusion of 1 ug/kg Fentanyl, 0.1 mg/kg Atracirium and 6-12 mg/kg/h Propofol.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Bouali Hospital

Full name of responsible person

Mahnaz Narimani Zamanabadi

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Bouali Hospital, Damavand Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

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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

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

Amirnezam Mir

Position

Medical student

Latest degree

Medical doctor

Other areas of specialty/work

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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

No more information

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

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

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

Data Dictionary

No - There is not a plan to make this available