

Clinical Trial Protocol

Iranian Registry of Clinical Trials

14 Jul 2026

Comparison of the Effect of Remifentanyl and Nitroglycerin on Intraoperative Blood Pressure and Complications During and After Rhinoplasty

Protocol summary

Study aim

Comparison of the effect of remifentanyl and nitroglycerin on intraoperative blood pressure and complications during and after rhinoplasty in the surgical center under the supervision of Shahrekord University of Medical Sciences

Design

This study is a double-blind clinical trial that was conducted in 1398 after the approval of the proposal and obtaining permission. First, 50 patients who volunteered for rhinoplasty surgery referred to Dr. Afzali Shahrekord clinic and had inclusion criteria and no exclusion criteria, were selected and randomly divided into two groups of 25 based on a random number table.

Settings and conduct

First, 50 volunteer patients for rhinoplasty surgery referred to Dr. Afzali Shahrekord clinic and having inclusion criteria and no exclusion criteria were selected and randomly divided into two groups of 25 based on a table of random numbers. Location of surgery: Surgery centers under supervision Shahrekord Medical University

Participants/Inclusion and exclusion criteria

Age between 18 and 45 years Classification of the American Anesthesia Association in Physical Classes 1 and 2 Satisfaction of the company in the project No history of bleeding disorders in the patient No history of hypertension in the patient Do not take drugs that alter coagulation profiles such as aspirin Platelet counts

Intervention groups

Patients referred for rhinoplasty with concomitant anesthesia to control blood pressure in the first group of remifentanyl (0.1-0.3 µg / kg / min) and in the second group of nitroglycerin (0.5-1 µg / min) Kg / min) and their blood pressure is monitored before, during and after surgery and the effect of these two drugs is compared.

Main outcome variables

blood pressure

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210508051228N1**

Registration date: **2021-06-19, 1400/03/29**

Registration timing: **retrospective**

Last update: **2021-06-19, 1400/03/29**

Update count: **0**

Registration date

2021-06-19, 1400/03/29

Registrant information

Name

Ali Hasanpourdehkordi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 38 3333 0064

Email address

a.dehkordi1398@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-23, 1398/07/01

Expected recruitment end date

2020-09-21, 1399/06/31

Actual recruitment start date

2019-09-23, 1398/07/01

Actual recruitment end date

2020-09-21, 1399/06/31

Trial completion date

2020-12-20, 1399/09/30

Scientific title

Comparison of the Effect of Remifentanyl and Nitroglycerin on Intraoperative Blood Pressure and Complications During and After Rhinoplasty

Public title

Comparison of the Effect of Remifentanyl and Nitroglycerin on Intraoperative Blood Pressure and Complications During and After Rhinoplasty

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

1-Age between 18 and 45 years 2- Classification of the American Anesthesia Association in Physical Classes 1 and 2 3- Satisfaction of the company in the project 4-No history of bleeding disorders in the patient 5-No history of hypertension in the patient 6-Do not take drugs that alter coagulation profiles such as aspirin 7-Platelet counts and normal coagulation tests

Exclusion criteria:

Age

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

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **50**

Actual sample size reached: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Simple-individual randomization - 50 patients who volunteered for rhinoplasty surgery referred to Dr. Afzali Clinic in Shahrekord and with inclusion criteria and no exclusion criteria were selected and randomly divided into two groups of 25 based on a random number table.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is a double-blind clinical trial that was conducted in 1398 after the approval of the proposal and obtaining permission . First, 50 patients who volunteered for rhinoplasty surgery referred to Dr. Afzali Shahrekord clinic and had inclusion criteria and no exclusion criteria, were selected and randomly divided into two groups of 25 based on a random number table.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahrekord University of Medical Sciences

Street address

Rahmatieh

City

Shahrekord

Province

Chahar-Mahal-va-Bakhtiari

Postal code

8813833435

Approval date

2019-06-09, 1398/03/19

Ethics committee reference number

IR.SKUMS.REC.1398.076

Health conditions studied

1

Description of health condition studied

Rhinoplasty

ICD-10 code

Y81

ICD-10 code description

General- and plastic-surgery devices associated with adverse incidents

Primary outcomes

1

Description

blood pressure

Timepoint

Before, during and after rhinoplasty

Method of measurement

The vital signs monitoring device of Mizan Teb Company

Secondary outcomes

1

Description

The surgeon's satisfaction with the surgical site

Timepoint

Before, during and after rhinoplasty

Method of measurement

Vital Signs Monitoring Company of Mizan Teb Company

Intervention groups

1

Description

Intervention group 1: People receiving remifentanyl

0.1-0.3 µg / kg / min at the same time as anesthesia before and during rhinoplasty Intervention

Category

Treatment - Surgery

2

Description

"Intervention group 2:" Receiving nitroglycerin (0.5 -1.0 mg / kg / min) at the same time as anesthesia before and during rhinoplasty

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Clinic

Full name of responsible person

Marzieh Naderi

Street address

Ordibehesht Building

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Dr.afzali.sl@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Dr. Masoumeh Moezzi

Street address

Kashani Street

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Shahrekord

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Chahar-Mahal-va-Bakhtiari

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Email

mmoezzi@skums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shahre-kord 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

Shahre-kord University of Medical Sciences

Full name of responsible person

Dr. Lotfollah Afzali

Position

Research Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Plastic and Cosmetic Surgeon

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahre-kord University of Medical Sciences

Full name of responsible person

Dr. Ali Hassanpourdehkordi

Position

Research Consultant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Nursery

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Person responsible for updating data**Contact****Name of organization / entity**

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Latest degree

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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

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

Not applicable

Title and more details about the data/document

In the full text of the thesis

When the data will become available and for how long

After the explanation of the thesis

To whom data/document is available

Researchers and students of the centers

Under which criteria data/document could be used

Referral of research work references

From where data/document is obtainable

University Library

What processes are involved for a request to access data/document

Submit request and review

Comments