Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Aug 2026

Investigating the effect of Remifentanil and Labtalol, in combination with Propofol, on hemodynamic changes in nasal endoscopy

Protocol summary

Study aim
to investigate hemodynamic changes in the injection of Remifentanil with Labetalol, combined with Propofol in nasal endoscopy

Design
randomized trial; without blinding; in parallel; has a control group; Phase 3; Randomization using colored cards

Settings and conduct
It is performed on patients who are candidates for nose surgery and who refer to educational-therapeutic centers of Qazvin University of Medical Sciences and are included in the study randomly without blinding.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Willingness to participate in research with informed consent after giving necessary and sufficient explanations about the study; aged between 15 and 60 years; no history of surgery; Not having a chronic mental or physical illness; Not having vision and hearing problems and other disabilities; Absence of allergy to Remifentanil, Profol or Labtalol; Absence of pregnancy, breastfeeding or abortion less than three months.
Exclusion criteria: Unwillingness to cooperate in the study; Heart diseases and HTN; Liver diseases.

Intervention groups
Patients who met the necessary conditions, after full training by an Anesthesiologist and filling in the patient's informed personal consent form, entered the study and randomly entered into one of the two test groups A (Remifentanil in combination with Propofol) and test group B (Labetalol in combination with Propofol) be.

Main outcome variables
Hemodynamic changes, bleeding rate, arrhythmia rate

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221119056535N1**
Registration date: **2022-12-18, 1401/09/27**
Registration timing: **prospective**

Last update: **2022-12-18, 1401/09/27**
Update count: **0**

Registration date
2022-12-18, 1401/09/27

Registrant information

Name
Khashayar Shahverdi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 21 2270 7778

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-12-20, 1401/09/29

Expected recruitment end date
2023-02-18, 1401/11/29

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the effect of Remifentanil and Labtalol, in combination with Propofol, on hemodynamic changes in nasal endoscopy

Public title

Investigating the effect of Remifentanil and Labtalol on hemodynamic changes

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Willingness to participate in research with informed consent after giving necessary and sufficient explanations about the study The age of the person should be between 15 and 60 years There is no history of surgery and it is the patient's first surgery Not having a chronic mental or physical illness (schizophrenia, diabetes, etc.) Not having vision and hearing problems and other disabilities No allergy to Remifentanil, Profol and Labtalol Absence of pregnancy, breastfeeding and abortion less than 3 months

Exclusion criteria:
Heart diseases and HTN Liver diseases (cirrhosis, hepatitis, etc.)

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

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients who met the necessary conditions, after completing the personal informed consent form to the trial in a simple random manner using blue and red color cards placed in a container and the patient himself chooses the color of his choice. They enter one of the two experimental and control groups.

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Qazvin University of Medical Sciences

Street address
Unit 1, 10 floor, Kasra tower 5, Nokhbegan square

City
Qazvin

Province
Qazvin

Postal code
3415866563

Approval date
2022-11-16, 1401/08/25

Ethics committee reference number
IR.QUMS.REC.1401.239

Health conditions studied

1

Description of health condition studied
Hemodynamic changes

ICD-10 code

ICD-10 code description

2

Description of health condition studied
Bleeding rate

ICD-10 code

ICD-10 code description

3

Description of health condition studied
arrhythmia

ICD-10 code
I49.9

ICD-10 code description
Cardiac arrhythmia, unspecified

Primary outcomes

1

Description
Bleeding

Timepoint
First, three minutes after the start of induction, then three and five minutes and then ten minutes

Method of measurement
ECG, pulse oximeter, non-invasive blood pressure measurement

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Patients who met the necessary conditions, after full training by an anesthesiologist and filling in the patient's informed personal consent form, entered the study and were randomly assigned to experimental group A (remifentanil combined with

propofol). Dose of drugs: Remifentanil: the onset of anesthesia starts with 1 to 5 mcg/kg/minute. If an endotracheal tube is inserted for the patient within 8 minutes, an initial dose of 1 mcg/kg in 30-60 Seconds are also given to maintain anesthesia: 1 mcg/kg/min can be infused every 2-5 minutes. The dose can be increased by 25-100% or decreased by 25-50% every 2-5 minutes. Propofol: within 15 seconds and with a dose of 2 mg/kg based on the weight of the study group, it is injected through a tee along with 10 cc of normal saline.

Category

Treatment - Drugs

2

Description

Intervention group 2: Patients who met the necessary conditions, after full training by the anesthesiologist and filling out the patient's informed personal consent form, entered the study and were randomly assigned to experimental group B (labtalol in combination with propofol). Dosage of drugs: labtalol: 20 mg intravenous injection once and then, if there is no effect, as an infusion of 2-0.5 mg per minute up to a maximum dose of 300 mg and propofol: within 15 seconds and with a dose of 2 mg/kg based on The weight of the study group is injected with 10 cc of normal saline through a tee

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Qods hospital

Full name of responsible person

Khashayar Shahverdi

Street address

Quds Educational and Medical Center, Quds Square, the beginning of East Palestine, Shahid Beheshti Blvd., Qazvin

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Qazvin University of Medical Sciences

Full name of responsible person

Dr. Seyed Mehdi Mirhashmi

Street address

Research and Technology Vice-Chancellor of Qazvin University of Medical Sciences, Mavedat sub-district, Shahid Beheshti Blvd.

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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

Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Khashayar Shahverdi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

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Position
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Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Medical doctor

Other areas of specialty/work
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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
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