# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

19 Sep 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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**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

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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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researchdpt@qums.ac.ir

**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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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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