

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

19 Jun 2026

### Comparison of the effect of low-dose naloxone infusion on hemodynamic factors and surgical field bleeding in patients under general anesthesia with remifentanil and propofol infusion.

#### Protocol summary

##### Study aim

Comparison of the effect of low-dose naloxone infusion on hemodynamic factors and surgical field bleeding in patients under general anesthesia with remifentanil and propofol infusion.

##### Design

This study is a controlled clinical trial with parallel, double-blind, randomized groups on 114 patients. Block randomization method is used for randomization.

##### Settings and conduct

This study is a randomized clinical trial and will be performed after the approval of the ethics committee of Tehran University of Medical Sciences. After prescribing premedication and standard monitoring, induction of anesthesia is performed. To maintain anesthesia, infusion of remifentanil (1 µg / kg / min) and propofol in a dose 150 µg / kg / min are used. In the intervention group, naloxone (0.25 g / kg / h) prepared in 10 ml of normal saline is infused during the operation using a syringe pump. In the control group, 10 ml of normal saline is infused using a syringe pump during the operation. Systolic and diastolic blood pressure, heart rate in the time before induction are recorded, then systolic and diastolic blood pressure, heart rate, cardiac output, stroke volume are recorded 15 minutes after induction and every 15 minutes until the end of the operation and in recovery. The surgeon's general satisfaction from the amount of bleeding during the operation at the surgical site is also evaluated and recorded.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients undergoing head and neck surgery  
Exclusion criteria: Patients addicted to Narcotics, Patients with heart failure or advanced heart disease, Patients with asthma

##### Intervention groups

Intervention group: Injection of low-dose naloxone

infusion (0.25µg/kg/h) in 10 ml of normal saline Control group : injection of 10 ml normal saline infusion

##### Main outcome variables

Dose of narcotics.the surgeon's satisfaction with the surgical bleeding

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20101122005225N10**

Registration date: **2022-05-09, 1401/02/19**

Registration timing: **registered\_while\_recruiting**

Last update: **2022-05-09, 1401/02/19**

Update count: **0**

##### Registration date

2022-05-09, 1401/02/19

##### Registrant information

##### Name

Seyed mohammad Mireskandari

##### Name of organization / entity

Tehran University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2261 8931

##### Email address

mireskandari@sina.tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2022-04-21, 1401/02/01

##### Expected recruitment end date

2022-10-22, 1401/07/30  
**Actual recruitment start date**  
empty  
**Actual recruitment end date**  
empty  
**Trial completion date**  
empty

**Scientific title**  
Comparison of the effect of low-dose naloxone infusion on hemodynamic factors and surgical field bleeding in patients under general anesthesia with remifentanyl and propofol infusion.

**Public title**  
The effect of naloxone on hemodynamic factors and bleeding rate in patients under general anesthesia.

**Purpose**  
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

Patients undergoing head and neck surgery

**Exclusion criteria:**

Patients addicted to Narcotics Patients with heart failure or advanced heart disease Patients with asthma

**Age**  
From **18 years** old to **65 years** old

**Gender**  
Both

**Phase**  
3

**Groups that have been masked**

- Care provider
- Data analyser

**Sample size**  
Target sample size: **114**

**Randomization (investigator's opinion)**  
Randomized

**Randomization description**  
In this study, we use the block randomization method so that after selecting patients according to the inclusion and exclusion criteria by selecting numbers from the table of random numbers and adapting to the blocks, patients are divided into study groups. To randomize the two treatment methods, we create 4 blocks in six different states, then select a number using the table of numbers, and determine the study groups by matching the numbers with the blocks. For example, if the first digit of our number is 1 to 6, select a block and the division is done, but if, for example, our number is 94071, the digit 9 is not valid and we select the next digit. Here, based on the block 4, we divide patients into groups. 1. TTCC 2. TCTC 3. TCCT 4. CCTT 5. CTCT 6. CTTC

**Blinding (investigator's opinion)**  
Double blinded

**Blinding description**  
In this study, people who are responsible for patient care and analysis of statistical data do not know about the treatment process and study groups, and information is provided to them in groups A and B

**Placebo**  
Used  
**Assignment**  
Parallel  
**Other design features**

**Secondary Ids**  
empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics committee of Tehran University of Medical Sciences

**Street address**

Corner of Ghods Street, Keshavarz Boulevard, the headquarters of Tehran University of Medical Sciences

**City**

Tehran

**Province**

Tehran

**Postal code**

8874113911

**Approval date**

2021-09-01, 1400/06/10

**Ethics committee reference number**

IR.TUMS.IKHC.REC.1400.214

**Health conditions studied**

**1**

**Description of health condition studied**

Head and neck surgery

**ICD-10 code**

C82.51

**ICD-10 code description**

Diffuse follicle center lymphoma, lymph nodes of head, face, and neck

**Primary outcomes**

**1**

**Description**

Dose of narcotics

**Timepoint**

During the operation

**Method of measurement**

View and record

**Secondary outcomes**

**1**

**Description**

Surgeon satisfaction with bleeding during surgery

#### **Timepoint**

During the operation

#### **Method of measurement**

Questionnaire

## **Intervention groups**

### **1**

#### **Description**

Intervention group: This study is a randomized clinical trial and will be performed after the approval of the ethics committee of Tehran University of Medical Sciences. After prescribing premedication and standard monitoring, induction of anesthesia is performed. In the intervention group, naloxone (manufactured by Tolid darou pharmaceutical company) is prepared in a dose (0.25 g / kg / h) in 10 ml of normal saline and is infused during the operation using a syringe pump. Systolic and diastolic blood pressure, heart rate in the time before induction are recorded, then systolic and diastolic blood pressure, heart rate, cardiac output, stroke volume are recorded 15 minutes after induction and then every 15 minutes until the end of the operation and in recovery .The surgeon's overall satisfaction with the amount of bleeding during the operation at the surgical site is also assessed and recorded.

#### **Category**

Treatment - Drugs

### **2**

#### **Description**

Control group: This study is a randomized clinical trial and will be performed after the approval of the ethics committee of Tehran University of Medical Sciences. After prescribing premedication and standard monitoring, induction of anesthesia is performed. In the control group, 10 ml of normal saline is infused using a syringe pump during the operation. Systolic and diastolic blood pressure, heart rate in the time before induction are recorded, then systolic and diastolic blood pressure, heart rate, cardiac output, stroke volume are recorded , 15 minutes after induction and every 15 minutes until the end of the operation and in recovery. The surgeon's overall satisfaction with the amount of bleeding during the operation at the surgical site is also assessed and recorded.

#### **Category**

Placebo

## **Recruitment centers**

### **1**

#### **Recruitment center**

##### **Name of recruitment center**

Imam Khomeini Hospital

##### **Full name of responsible person**

Seyed Mohammad Mireskandari

##### **Street address**

No4, Yasaman Alley, Goleyakh Alley, Basiri St., Shariati Ave., Tehran

#### **City**

Tehran

#### **Province**

Tehran

#### **Postal code**

۱۴۱۹۷۳۳۱۴۱

#### **Phone**

+98 21 2261 8931

#### **Email**

mireskandari@sina.tums.ac.ir

## **Sponsors / Funding sources**

### **1**

#### **Sponsor**

##### **Name of organization / entity**

Tehran University of Medical Sciences

##### **Full name of responsible person**

Akbar Fotouhi

##### **Street address**

No4, Yasaman Alley, Goleyakh Alley, Basiri St., Shariati Ave., Tehran

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##### **Phone**

+98 21 2261 8931

##### **Email**

vcr@tums.ac.ir

#### **Grant name**

#### **Grant code / Reference number**

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

Yes

#### **Title of funding source**

Tehran 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**

Tehran University of Medical Sciences

##### **Full name of responsible person**

Seyed Mohammad Mireskandari

##### **Position**

Associate professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

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Seyed Mohammad Mireskandari

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**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Seyed Mohammad Mireskandari

**Position**

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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**

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