Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Sep 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 remifentanil 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

City

Tehran

Province

Tehran

Postal code

۱۴۱۹۷۳۳۱۴۱

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
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

Person responsible for scientific 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
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

Person responsible for updating data

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
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

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