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

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Akbar Fotouhi

Street address

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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

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 updating data

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Position

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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