

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of Remifentanil use in spinal surgery with and without ANI(analgesia nociception Index) monitoring guidance

Protocol summary

Study aim

Comparison of Remifentanil use in spinal surgery under general anesthesia in two groups under ANI monitoring and without ANI monitoring

Design

Block and single-blind randomized clinical trial in phase 3 on 60 patients undergoing general anesthesia for spinal surgery, in two parallel control and intervention groups, with and without ANI monitoring.

Settings and conduct

In this study, a single-blind randomized clinical trial for a researcher, by not stating the size of randomization blocks, patients undergoing general anesthesia for spinal surgery at Sina Hospital in Tehran were randomly divided into two groups with and without ANI monitoring. During surgery, depending on the BIS, between 40 and 60 infusions of propofol are administered in both groups and according to ANI values, between 50 and 70 infusions of remifentanil are prescribed in the group under ANI guidance.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients between 18 and 70 years old, patients candidates for spinal surgery, ASA grade I-II and consent to study. Exclusion criteria: Patients with arrhythmia, patients taking beta-blockers, patients with neuromuscular diseases, diabetics and pregnant women, patients for whom pre- or postoperative ANI monitoring should be discontinued, patients who require Transfer to ICU without postoperative awakening, patients who had received medication before the intervention, lack of patient cooperation, drug addiction.

Intervention groups

Control group: Candidate patients for spinal surgery under general anesthesia without ANI monitoring;
Intervention group: Candidate patients for spinal surgery under general anesthesia under the guidance of ANI monitoring

Main outcome variables

The amount of remifentanil used during surgery; the

amount of pain in recovery; The incidence of complications due to the administration of Remifentanyl.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180303038923N1**

Registration date: **2022-07-05, 1401/04/14**

Registration timing: **retrospective**

Last update: **2022-07-05, 1401/04/14**

Update count: **0**

Registration date

2022-07-05, 1401/04/14

Registrant information

Name

Farsad Imani

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4402 6720

Email address

imanifar@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-05-21, 1397/02/31

Expected recruitment end date

2019-06-19, 1398/03/29

Actual recruitment start date

2018-05-21, 1397/02/31

Actual recruitment end date

2019-06-19, 1398/03/29

Trial completion date

2020-08-19, 1399/05/29

Scientific title

Comparison of Remifentanyl use in spinal surgery with and without ANI(analgesia nociception Index) monitoring guidance

Public title

Comparison of Remifentanyl use in spinal surgery with and without ANI monitoring guidance

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients between 18 and 70 years Patients candidate for spine surgery ASA Grade I-II Consent to enter the study

Exclusion criteria:

Patients taking beta-blocker drugs

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Actual sample size reached: **58**

Randomization (investigator's opinion)

Randomized

Randomization description

The eligible patients were randomly assigned to the treatment and control groups using balanced block randomization with a block size of four. For this purpose, the treatment and control groups were randomly assigned to letters A and B. Thus, for each block of four patients, two sequence different assignments were made for each treatment. Six sheets of paper were used. In the papers were written all the possible states, i.e. Paper No. 1 for AAB, Paper No. 2 for ABAB, Paper No. 3 for ABBA, Paper No. 4 for BBAA, Paper No. 5 for BABA, and Paper No. 6 or BAAB. Then the number were selected randomly via table of random numbers. According to number of selected papers, the patients respectively were in the treatment or 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 Tehran university of medical science in

Street address

Sina hospital, Imam Khomeini St, Tehran

City

Tehran

Province

Tehran

Postal code

1136746911

Approval date

2019-09-02, 1398/06/11

Ethics committee reference number

IR.TUMS.MEDICINEREC.1398.479

Health conditions studied**1****Description of health condition studied**

Remifentanyl use in surgery with Analgesia Nociception Index

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Dosage of remifentanyl during surgery

Timepoint

During surgery

Method of measurement

The amount of remifentanyl consumed

Secondary outcomes**1****Description**

The rate of pain in recovery in patients

Timepoint

10, 20, 30 and 60 minutes during recovery

Method of measurement

Visual Analogue Scale

2**Description**

Further drop in arterial blood saturation below 90% for 60 seconds

Timepoint

10, 20, 30 and 60 minutes during recovery

Method of measurement

3**Description**

Complications of fentanyl remedies

Timepoint

During recovery

Method of measurement

According to the recovery nurse

4**Description**

Global Satisfaction of patients at the end of recovery

Timepoint

At the end of recovery

Method of measurement

Based on 5 point criteria (poor, average, good, very good and excellent)

Intervention groups**1****Description**

Control group: Patients who are candidates for spinal surgery who undergo general anesthesia without ANI monitoring.

Category

Treatment - Other

2**Description**

Intervention group: Patients who are candidates for spinal surgery who undergo general anesthesia under the guidance of ANI monitoring.

Category

Treatment - Other

Recruitment centers**1****Recruitment center****Name of recruitment center**

Sina hospital

Full name of responsible person

Farsad Imani

Street address

Sina hospital, Imam Khomeini St

City

Tehran

Province

Tehran

Postal code

1136746911

Phone

+98 21 6312 1278

Email

Imanifar@tums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Farsad imani

Street address

Sina hospital, Imam Khomeini St.

City

Tehran

Province

Tehran

Postal code

1136746911

Phone

+98 21 6312 1278

Email

imanifar@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

Farsad Imani

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

Street address

Sina hospital, Imam Khomeini St

City

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Province

Tehran

Postal code

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Phone

+98 21 6312 1278

Email

imanifar@tums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Farsad Imani

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Postal code

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Phone

+98 21 6312 1278

Email

imanifar@tums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Farsad Imani

Position

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Anesthesiology

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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

Not applicable

Data Dictionary

Not applicable