

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Obtainability of intraoperative remifentanil infusion induced hyperaesthesia and compare control methods of post op pain with Morphine or Apotel.

Protocol summary

Summary

Eighty seven patients undergoing elective spine surgery with device are studied. The study examined patients in three groups of each 30 in A, B, C groups in a double-blind Randomized Clinical Trial. Exclusion criteria: acute or chronic renal failure; liver failure; nerve paralysis (Hemiplegia); spinal nerve injury; COPD (chronic obstructive pulmonary disease) and patient dissatisfaction. Moreover, patients addicted to drugs, alcohol or other drugs do not include in the study. All patients or their guardians consent to be in the study and there is no obligations. Essential training about the standard visual analogue scale (VAS) is taught to patients in which the VAS shows to the patient marked 0-10 and 0 means No Pain and number 10 shows the Worst pain unbearable. Furthermore, to all patients Pulse oximeter, Non Invasive and Invasive blood pressure, end-tidal CO₂ and temperature monitoring are given in the operation room. BIS monitoring is performed for all patients. After preoxygenation with facial mask and premedication with Midazolam 0.03 mg/kg and 1-3 microgram /kg Fentanyl patients will anesthetized by Propofol 2 Mg/Kg and Atracurium 0.5 mg/kg; moreover, after 3 minutes patient will intubate with tracheal tube. Anesthesiologist and surgery team is the same for all patients. For maintenance propofol 100-150 microgram/kg/hr and Atracurium 0.2 mg per every 30 minutes is used. The analgesia for Group A Fentanyl and for group B and C Remifentanil is used. Moreover, at the end of 20 minutes of surgery, Apotel 15 mg/kg is used for group A and B but in group C is morphine 0.05 mg/kg. 30 minutes after patients stay at recovery room, 6, 12, 24, 48 after surgery vital signs, Visual Analogue Scale, Ramsey Sedation Score and the absence of existence of Post Operation Vomiting and nausea and Respiratory depression due to the prescribing morphine will be measured.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014072618597N1**

Registration date: **2015-03-12, 1393/12/21**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-03-12, 1393/12/21

Registrant information

Name

Reza Shariat Moharari

Name of organization / entity

Sina Hospital

Country

Iran (Islamic Republic of)

Phone

+98 911 331 2758

Email address

moharari@tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2015-02-20, 1393/12/01

Expected recruitment end date

2015-08-21, 1394/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Obtainability of intraoperative remifentanyl infusion induced hyperalgesia and compare control methods of post op pain with Morphine or Apotel.

Public title

Obtainability of intraoperative remifentanyl infusion induced hyperalgesia and compare control methods of post op pain with Morphine or Apotel.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients between the age of 15-75; with ASA class I or II. Exclusion criteria: patients with acute kidney failure; chronic kidney failure; hepatic dysfunction; patients addicted to drugs; alcohol and other medications.

Age

From **15 years** old to **75 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **87**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran University of Medical Sciences

Street address

Tehran University Of Medical Sciences, Taleghani St, Enghelab Sq, Tehran, Iran

City

Tehran

Postal code

Approval date

2014-12-06, 1393/09/15

Ethics committee reference number

92-04-30-27234-132500

Health conditions studied

1

Description of health condition studied

Patients undergoing spinal surgery in which device will be used

ICD-10 code

M47-M48

ICD-10 code description

Spondylosis and Other spondylopathies

Primary outcomes

1

Description

Pain

Timepoint

At Recovery Room, 6, 12, 24,48 hours after surgery

Method of measurement

Visual Analogue Scale

2

Description

Ramsey Sedation Scale

Timepoint

Recovery, 6, 12, 24,48 hours after surgery

Method of measurement

Ramsey Sedation Score Table

3

Description

Morphine consumption after surgery

Timepoint

Recovery, 6, 12, 24,48 hours after surgery

Method of measurement

Milligram

Secondary outcomes

1

Description

Respiratory Depression

Timepoint

At Recovery Room, 6,12,24,48 hrs. after surgery

Method of measurement

Clinical Observation

2

Description

Post Operation Vomiting and Nausea (PONV)

Timepoint

At Recovery Room, 6,12,24,48 hrs. after surgery

Method of measurement

Standard Scale

Intervention groups

1

Description

Group I : Remifentanil (maintenance) and Apotel (end of surgery) According Methods

Category

Treatment - Drugs

2

Description

Group II : Remifentanil (maintenance) , Morphine (end of surgery) According Methods

Category

Treatment - Drugs

3

Description

Group III : Fentanyl (maintenance) Apotel (end of surgery) According Methods

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Dr. Reza Shariat Moharari

Street address

Sina Hospital, Hassan Abad Sq, Imam Khomeini St, Tehran, Iran

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Reza Shariat Moharari

Street address

Taleghani St, Qods St, Enghlab Sq, Tehran, Iran

City

Tehran

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

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Sina Hospital

Full name of responsible person

Elahe sahraei

Position

Anesthesia Student

Other areas of specialty/work

Street address

Sina Hospital, Imam khomeini St, Imam khomeini Sq, Tehran, Iran

City

Tehran

Postal code

Phone

+98 919 550 5701

Fax

Email

e.sahrai@ymail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Sina Hospital

Full name of responsible person

Dr. Reza Shariat Moharari

Position

Associate Proffesor-Anesthesiologist

Other areas of specialty/work

Street address

Sina Hospital, Imam khomeini St, Hassan Abad Sq, Tehran, Iran

City

Tehran

Postal code

Phone

+98 21 6634 8533

Fax

Email

moharari@tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Sina Hospital
Full name of responsible person
Elahe Sahraei
Position
Anesthesia student
Other areas of specialty/work
Street address
Sina Hospital, Hassan Abad Sq, Imam Khomeini St,
Tehran, Iran
City
Tehran
Postal code
Phone
+98 919 550 5701
Fax
Email
e.sahrai@ymail.com
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty