Clinical Trial Protocol
Iranian Registry of Clinical Trials

24 Jun 2026

Obtainability of intraoperative remifentanil infusion induced hyperagesia 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. Anethesiologist and surgery team is the same for all patients. For maitenance propofol 100-150 microgram\kg\hr and Atracurium 0.2 mg per every 30 minutes is used. The analgesia for Group A Fetanyl 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 Analouge 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
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Iran (Islamic Republic of)
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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 remifentanil infusion induced hyperagesia and compare control methods of post op pain with Morphine or Apotel.

Public title
Obtainability of intraoperative remifentanil infusion induced hyperalgesia and compare control methods pf 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
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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
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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
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
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Elahe sahraei
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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