Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Jul 2026

Evaluation of the efficacy of low-dose naloxone for the prevention of acute remifentanil-induced hyperalgesia in patients undergoing general anesthesia for hysterectomy

Protocol summary

Study aim

To evaluate the efficacy of adding low dose naloxone to intraoperative infusion of remifentanil in preventing the post-operative acute remifentanil induced hyperalgesia in laparotomic hysterectomy

Design

Randomized controlled, parallel groups, double blinded clinical trial, 75 patients undergoing , three groups of remifentanil-naloxone , remifentanil and control

Settings and conduct

After administration of pre-medication midazolam and fentanyl and lidocaine anesthesia was induced by propofol and atracurium After tracheal intubation, isoflurane and muscle relaxants are used for maintenance of anesthesia, when necessary. In this study, both the patients and the evaluators are blinded to the type of intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: ASA I-III patients; aged between 18 to 75 years scheduled for elective hysterectomy Exclusion criteria ; uncontrolled diabetes mellitus, neurologic disorders, psychologic disorders which needs treatment, inflammatory and renal diseases, drug abuse, routine use or taking NSAIDs, opioids, allergy or contraindication to anesthetic agents or pain medications, history of any type of chronic pain needs medical or interventional treatments and patients receiving ketamine, antipsychotic or gabapentinoids

Intervention groups

Remifentanil-Naloxone (patients receiving remifentanil 0.3 µg/kg/min and low dose naloxone 0.25 µg/kg/h in 50 ml normal saline, Remifentanil (patients receiving remifentanil 0.3 µg/kg/min), and control (patients receiving an infusion of 50 ml normal saline

Main outcome variables

The severity of hyperalgesia and allodynia is assessed by static tactile tests. The severity of pain in a static tactile test is reported as VAS. Patients are asked to grade their highest pain severity from 1 to 10 in 0.5, 1, 6,12, and 24 hours after surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20101122005225N8**
Registration date: **2020-08-21, 1399/05/31**
Registration timing: **retrospective**

Last update: **2020-08-21, 1399/05/31**
Update count: **0**

Registration date

2020-08-21, 1399/05/31

Registrant information

Name

Seyed mohammad Mireskandari

Name of organization / entity

Tehran University of Medical Sciences

Country

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+98 21 2261 8931

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-08-23, 1396/06/01

Expected recruitment end date

2019-02-19, 1397/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy of low-dose naloxone for the prevention of acute remifentanil-induced hyperalgesia in patients undergoing general anesthesia for hysterectomy

Public title

Efficacy of low-dose naloxone for the prevention of acute remifentanil-induced hyperalgesia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Female patients aged between 18 to 75 years ASA (American Society of Anesthesiologists) I-II patients Patients scheduled for elective hysterectomy

Exclusion criteria:

Uncontrolled diabetes mellitus Neurologic disorders Psychologic disorders which needs treatment Inflammatory and renal diseases Drug abuse Routine use or taking NSAIDs, opioids or other analgesics 48 hours prior to surgery Allergy or contraindication to anesthetic agents or pain medications, including NSAID’s, acetaminophen and opioids History of any type of chronic pain needs medical or interventional treatments Patient who develop any surgical or anesthetic complication, or need reoperation Patients receiving ketamine, antipsychotic or gabapentinoids

Age

From **18 years** old to **75 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomlely assigned into three equal groups using computer-generated random sequence and the sealed envelope method by an assistant not involved in the study

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, both the patients and the evaluators were blinded to the type of intervention. All drugs were labeled and similar in appearance. A trained nurse anesthetist collects the data in operating room and post anesthetic care unit and an anesthesia resident blinded to study groups collects the data in the ward

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

Vice Research office, Building no.1, Northern gate of the university, Poursina St. Qods St. Enqelab St.

City

Tehran

Province

Tehran

Postal code

1417653911

Approval date

2016-04-23, 1395/02/04

Ethics committee reference number

IR.TUMS.REC.1395.2450

Health conditions studied

1

Description of health condition studied

Hyperalgesia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

To decrease post operative hyperalgesia assessed by static tactile tests. The severity of pain in a static tactile test was reported as VAS

Timepoint

0.5, 2, 6, 12, and 24 hours after surgery.

Method of measurement

Static tactile test using a fine brush

Secondary outcomes

1

Description

Total morphin dose used in post operative period

Timepoint

During the 24 hour period after surgery

Method of measurement

Reported in Mg showed by analgesia pump

2

Description

The time of first rescue dose of morphine in post operative period

Timepoint

In post operative period

Method of measurement

It is reported as the time interval to the end of surgery

Intervention groups

1

Description

first Intervention group (Remifentanil-Naloxone group):patients receiving remifentanil 0.3 µg/kg/min and low dose naloxone 0.25 µg/kg/h in 50 ml normal saline

Category

Treatment - Drugs

2

Description

Second Intervention group(Remifentanil): patients receiving remifentanil 0.3 µg/kg/min)

Category

Treatment - Drugs

3

Description

Control group(control) : patients receiving an infusion of 50 ml normal saline

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital Complex

Full name of responsible person

Seyed Mohammad Mireskandari

Street address

Kheshavarz Boulvard, Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraeian

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

1

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 scientific inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is 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
Title and more details about the data/document
IPD collected for the primary outcome measure only
When the data will become available and for how long
starting in November 2025
To whom data/document is available
people working in academic institutions
Under which criteria data/document could be used
only for academic and research goals
From where data/document is obtainable
Via sending an Email for corresponding researcher
What processes are involved for a request to access data/document
proposal of the project and document of it's registration
Comments