Clinical Trial Protocol
Iranian Registry of Clinical Trials

15 Jun 2026

Study of the effect of different doses of Naloxone on postoperative hyperalgesia in patients receiving high-dose RemiFentanyl in hysterectomy surgeries

Protocol summary

Study aim
Determining the efficacy of different doses of naloxone on hyperalgesia after surgery in patients receiving high-dose Remi Fentanyl in hysterectomy surgeries
Design
Clinical trial with control group, parallel groups, double blind, randomized with 30 patients
Settings and conduct
Patients with hysterectomy candidates who underwent surgery at Rasoul Akram Hospital. They are anesthetized with naloxone. Participants are randomly assigned to three groups. Also, participants and assessors of the outcome will not be aware of the type of intervention.
Participants/Inclusion and exclusion criteria
Inclusion criteria: Patients candidate for hysterectomy, ASA 1&2, No drug allergy؛ Exclusion criteria: addiction, ālcohol consumption
Intervention groups
Control group: Normal saline with a dose of 0.2 cc per kg Intervention Group 1: Naloxone Infusion with a dose of 0.05 µg / kg / min Intervention Group 2: Naloxone Infusion with a dose of 0.02 µg / kg / min
Main outcome variables
VAS, Ramsy score, Pinprick test

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20180723040570N5**
Registration date: **2020-06-27, 1399/04/07**
Registration timing: **prospective**

Last update: **2020-06-27, 1399/04/07**
Update count: **0**
Registration date
2020-06-27, 1399/04/07

Registrant information
Name
Nasim Nikoubakht
Name of organization / entity
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2020-07-21, 1399/04/31
Expected recruitment end date
2021-06-22, 1400/04/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Study of the effect of different doses of Naloxone on postoperative hyperalgesia in patients receiving high-dose RemiFentanyl in hysterectomy surgeries

Public title
Effects of different doses of Naloxone on postoperative hyperparathyroidism
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:

Patients candidate for hysterectomy ASA 1&2 No drug allergy

Exclusion criteria:

Addiction Alcohol consumption

Age

From **20 years** old to **80 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, all eligible patients were assigned to three groups using random sequence extraction from the computer (via www.randomization.com) and simple randomization. The resulting random numbers, i.e. the allocation of patients to groups, was concealed using sealed envelopes.

Blinding (investigator's opinion)

Double blinded

Blinding description

Participants and outcome assessors are unaware of the type of group and the type of intervention

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University of Medical Sciences, Milad tower, Hemmat highway, Tehran

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Tehran

Province

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Postal code

1449614535

Approval date

2020-01-28, 1398/11/08

Ethics committee reference number

IR.IUMS.FMD.REC.1398.483

Health conditions studied

1

Description of health condition studied

Hysterectomy

ICD-10 code

N99.3

ICD-10 code description

Prolapse of vaginal vault after hysterectomy

Primary outcomes

1

Description

Visual Analogue Scale

Timepoint

30 minutes before surgery and 1, 2 , 8 and 24 hours after surgery

Method of measurement

Patient's answer

2

Description

Ramsy score

Timepoint

30 minutes before surgery and 1, 2 , 8 and 24 hours after surgery

Method of measurement

Patient's answer

3

Description

Pinprick test

Timepoint

30 minutes before surgery and 1, 2 , 8 and 24 hours after surgery

Method of measurement

Patient's answer

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Naloxone infusion with a dose of 0.05 µg / kg / min will be arranged by the completion of the surgery. Naloxone is produced by "Tolid daro" company of Iran.

Category

Treatment - Drugs

2

Description

Intervention group 2: Naloxone Infusion with a dose of 0.02 µg / kg / min will be arranged by the completion of the surgery. Naloxone is produced by "Tolid daro" company of Iran.

Category

Treatment - Drugs

3

Description

Control group: Normal saline with a dose of 0.2 cc per kg will be injected instead of Naloxone.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hazrate Rasoole Akram hospital

Full name of responsible person

Nasim Nikoobakht

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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

Iran 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

Iran University of Medical Sciences

Full name of responsible person

Nasim Nikoubakht

Position

Assistant, Professor,

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is 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
All individual data of the participants in this study will be shared after unidentifiable individuals

When the data will become available and for how long
The access period will start from 2021to 2022

To whom data/document is available
Data will be available to researchers working in the university.

Under which criteria data/document could be used
Just for performing research

From where data/document is obtainable
Refer to the responsible person for accessing the data

What processes are involved for a request to access data/document
The data will be available one month after the responsible person's approval

Comments