

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Comparison of intraoperative opioid use in two opioid injections according to the pain score determined by the Analgesia nociception index (ANI) and conventional injections in laparoscopic gynecological surgery

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

Comparison of total intraoperative opioid use in two methods of opioid injection based on pain score determined by the Analgesia nociception index (ANI) device and injection with conventional method in laparoscopic gynecological surgeries in women

Design

Clinical trial with control group, with parallel groups, double-blind, randomized, phase 1 on 90 patients

Settings and conduct

Study place: Rasool Akram hospital; Type of blinding: double-blind; How to blind: The patient and the statistical analyzer are unaware of which analgesic method the patient has been used for analgesia.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Candidate of laparoscopic gynecological surgery, Age between 18-45 years, Body mass index (BMI) less than 25. Non-inclusion criteria: Having cardiac arrhythmia, Patients with central or autonomic neurological problems undergoing opioid treatment

Intervention groups

Intervention group: Opioid injection based on pain score determined by the device (Analgesia nociception index (ANI)). Control group: Opioid injection with conventional method

Main outcome variables

Total dose of opioid used, pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120814010599N30**

Registration date: **2021-09-20, 1400/06/29**

Last update: **2021-09-20, 1400/06/29**

Update count: **0**

Registration date

2021-09-20, 1400/06/29

Registrant information

Name

Poupak Rahimzadeh

Name of organization / entity

Iran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 6650 9059

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-20, 1400/05/29

Expected recruitment end date

2022-02-18, 1400/11/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of intraoperative opioid use in two opioid injections according to the pain score determined by the Analgesia nociception index (ANI) and conventional

injections in laparoscopic gynecological surgery

Public title

Comparison of intraoperative opioid use in two opioid injections by Analgesia nociception index (ANI) and conventional method

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Candidate of laparoscopic gynecological surgery Age between 18-45 years Body mass index (BMI) less than 25

Exclusion criteria:

Having cardiac arrhythmia Patients with central or autonomic neurological problems undergoing opioid treatment

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were randomly divided into two groups of analgesia with Analgesia nociception index(ANI) and conventional method using random allocation software. By selecting the simple randomization method in the randomization box and entering the determined total sample size in this software, numbers were given to the patients and the patients were allocated into two groups according to computer-generated numbers.

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient and the statistical analyzer were unaware of the analgesia methods the patient is using. Analgesia was performed by an anesthesiologist in the operating room for randomly selected patients. In this way, the patient was only aware of the analgesia being performed on him/her but was unaware of its type and also the statistical analyzer will receive the data in code A and B for the intervention groups.

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

Vice chancellor for research, Iran University of Medical Sciences, beside Milad Tower, Hemat highway

City

Tehran

Province

Tehran

Postal code

1449614535

Approval date

2021-05-17, 1400/02/27

Ethics committee reference number

IR.IUMS.FMD.REC.1400.145

Health conditions studied

1

Description of health condition studied

Pain

ICD-10 code

G89

ICD-10 code description

Pain, not elsewhere classified

Primary outcomes

1

Description

Total dose of opioid used during surgery

Timepoint

After surgery

Method of measurement

Patient file

Secondary outcomes

1

Description

Pain

Timepoint

At 1, 12 and 24 hours after surgery

Method of measurement

Visual analog scale

Intervention groups

1

Description

Intervention group: In the Analgesia nociception index (ANI) intervention group, control for analgesia of patients during the operation of remifentanyl (Produced by Exir) will be performed according to the pain score determined by the Analgesia nociception index (ANI) device. In the ANI group, two electrodes will be placed on the sternum and the left mid axillary line. Total remifentanyl consumption was recorded as micrograms. Intraoperative pain measurement will be performed with the same device that measures pain score under anesthesia. It should be noted that pain score is scored by analyzing by the device. The device will be continuously connected to the patient and in case of changes beyond the desired range, the patient will be injected with medication.

Category

Treatment - Drugs

2

Description

Control group: In this group conventional method will be done (drug injection if the patient expresses pain)

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Pain interventions operating room-Hazrat Rasool hospital

Full name of responsible person

Poupak Rahimzadeh

Street address

Anesthesiology and pain department, Rasool Akram hospital, Niyayesh St, Sattarkhan Blvd

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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

Poupak Rahimzadeh

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Fifth floor, Central headquarters, Iran University of Medical Sciences, Hemmat Highway

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Person responsible for scientific

inquiries

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Name of organization / entity

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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

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