Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Assessing analgesia in mixed administrations of ketorolac + low dose pethidine comparison with pethidine after elective laparotomy leading to colectomy

Protocol summary

Study aim

Assessing analgesia in mixed administrations of ketorolac + low dose pethidine comparison with pethidine after elective laparotomy leading to colectomy

Design

This study is a randomized clinical trial (randomized blocks) without blinding, which will be performed with the participation of 100 patients who are candidates for colectomy in Imam Reza Hospital (Tabriz). This study is in parallel groups and has 2-3 phases.

Settings and conduct

This clinical trial study will be performed with the participation of 100 patients in Imam Reza Hospital (Tabriz). Patients will be divided into two groups by random allocation (random blocks). This study is without blinding and patients are divided into two groups after surgery so that the first group will receive low-dose ketorolac + pethidine and the second group will receive pethidine intravenously after surgery.

Participants/Inclusion and exclusion criteria

Inclusion criteria include weight between 45 and 115 kg and candidate for elective laparotomy leading to colectomy, and exclusion criteria include gastritis, disorders, unknown bleeding, pregnant women, opioid addiction.

Intervention groups

100 patients who are candidates for colectomy surgery will be divided into two groups after random allocation by random block method. The first group will receive low-dose ketorolac + pethidine after surgery and the second group will receive pethidine after surgery. This study will be performed in Imam Reza Hospital (Tabriz) and blinding has not been performed in this study.

Main outcome variables

Pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190325043107N20**
Registration date: **2020-12-31, 1399/10/11**
Registration timing: **prospective**

Last update: **2020-12-31, 1399/10/11**
Update count: **0**

Registration date

2020-12-31, 1399/10/11

Registrant information

Name

Mehdi Khanbabayi Gol

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3334 7054

Email address

khanbabayimehdi69@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-01-19, 1399/10/30

Expected recruitment end date

2021-03-20, 1399/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Assessing analgesia in mixed administrations of ketorolac + low dose pethidine comparison with pethidine after elective laparotomy leading to colectomy

Public title
ketorolac + low dose pethidine comparison with pethidine after elective laparotomy leading to colectomy
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
Weight between 45 to 115 kg Candidate elective laparotomy leading to colectomy
Exclusion criteria:
Getting gastritis Having unknown bleeding disorders Pregnant women Opioid addiction
Age
No age limit
Gender
Both

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be divided into two groups by random allocation method. The balanced (permuted) block randomization will be used for random allocation and patients will be divided into two groups of ketorolac + pethidine and pethidine ; Thus, first 6 possible modes of blocks (BAAB, ABBA, BABA, AABB, ABAB, BBAA) were listed and each block was assigned a number from 1 to 0. Then, a number between 1 and 0 was randomly selected and the subjects were assigned to the experimental group (A) and placebo (B) based on the relevant block and the selected number.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences
Street address
Tabriz University of Medical Sciences, Azadi Ave
City
Tabriz
Province
East Azarbaijan
Postal code
5165665631
Approval date
2020-01-20, 1398/10/30
Ethics committee reference number
IR.TBZMED.REC.1398.1163

Health conditions studied

1

Description of health condition studied
Pain
ICD-10 code
G89.29
ICD-10 code description
Other chronic pain

Primary outcomes

1

Description
Pain
Timepoint
The intervention will start immediately after the end of the surgery and will continue for up to two days after the surgery. The study variable will be measured every six hours from the beginning of the study for three days with the help of VAS instrument.
Method of measurement
VAS

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Patients will be randomly assigned to this group and will receive ketrolac (4 mg) + pethidine (40 mg) intravenously every 8 hours after elective colectomy; The severity of the pain will then be measured using a VAS instrument every eight hours.
Category
Treatment - Drugs

2

Description
Intervention group: Intervention group: Patients will be randomly assigned to this group and will receive pethidine (40 mg) intravenously every 8 hours after

elective colectomy; The severity of the pain will then be measured using a VAS instrument every eight hours.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Reza Hospital

Full name of responsible person

Touraj Asvadi

Street address

Imam Reza Hospital, Azadi Ave

City

Tabriz

Province

East Azarbaijan

Postal code

6165665631

Phone

+98 41 3335 5921

Email

T.asvadi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Abolghasem Jouyban

Street address

Tabriz University of Medical Sciences, Azadi Ave

City

Tabriz

Province

East Azarbaijan

Postal code

5165665631

Phone

+98 41 3335 7310

Email

Ajouyban@hotmail.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

Mehdi Khanbabayi Gol

Position

MSc in Nursing Education

Latest degree

Master

Other areas of specialty/work

Nursery

Street address

Imam Reza Hospital, Azadi Ave

City

Tabriz

Province

East Azarbaijan

Postal code

5981764863

Phone

+98 41 3334 7054

Fax

Email

Khanbabayimehdi69@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Mehdi Khanbabayi Gol

Position

MSc in Nursing Education

Latest degree

Master

Other areas of specialty/work

Nursery

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Person responsible for updating data

Contact

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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