Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Jul 2026

Comparison of the effectiveness of two combined drug regimens of venous ketorolac and diclofenac suppository in comparison with venous ketorolac alone on reducing pain after abdominal surgery under general anesthesia

Protocol summary

Study aim
Comparison of the effectiveness of two combination regimens of intravenous ketorolac and diclofenac suppository compared to intravenous ketorolac alone on reducing pain after abdominal surgery with general anesthesia

Design
Clinical trial, with parallel groups, double-blind, randomized, on 44 patients, using a table of random numbers

Settings and conduct
In the field of pain reduction after surgery, at Amirul Munin Hospital in Tehran, on two groups of 22 people, a double-blind study was conducted in which neither the patients nor the surgeon will know about the randomization method and the treatment protocol.

Participants/Inclusion and exclusion criteria
Entry: age over 18 years, undergoing all kinds of elective abdominal surgeries under general anesthesia, anesthesia class one and two Non-entry: the presence of any disease limiting the use of NSAID (patients with gastrointestinal, liver, kidney disorders); occurrence of surgery and anesthesia complications.

Intervention groups
Comparison of the effectiveness of two combination regimens of intravenous ketorolac and diclofenac suppository compared to intravenous ketorolac alone on reducing pain after abdominal surgery with general anesthesia

Main outcome variables
Comparing the effectiveness of Ketorolac and Diclofenac on reducing pain after abdominal surgery with general anesthesia

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230425057992N1**
Registration date: **2023-05-16, 1402/02/26**
Registration timing: **registered_while_recruiting**

Last update: **2023-05-16, 1402/02/26**
Update count: **0**

Registration date
2023-05-16, 1402/02/26

Registrant information

Name
Seyede zahra Seyf

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 4496 5783

Email address
zahra.seyf7596@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-12-22, 1401/10/01

Expected recruitment end date
2023-05-31, 1402/03/10

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
Comparison of the effectiveness of two combined drug regimens of venous ketorolac and diclofenac suppository in comparison with venous ketorolac alone on reducing pain after abdominal surgery under general anesthesia

Public title
Comparison of the effectiveness of ketorolac and diclofenac on reducing pain after surgery

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Age over 18 years, undergoing all kinds of elective surgeries of the abdominal area under general anesthesia, anesthesia class one and two

Exclusion criteria:
1- Existence of any disease limiting the use of NSAID (patients with gastrointestinal, liver, kidney disorders) 2- Incidence of surgery and anesthesia complications

Age
From **18 years** old

Gender
Both

Phase
2

Groups that have been masked

- Participant
- Care provider

Sample size
Target sample size: **44**

Randomization (investigator's opinion)
Randomized

Randomization description
This study requires 44 patients to be divided into two groups and 22 patients will be placed in each group. For this purpose, the table of random numbers has been used as follows: In the table of random numbers, a number is chosen randomly with the eyes closed and by shaking the tip of the pen. Then this number is the starting point, and from this number numbers are recorded from the bottom to the top and assigned to different groups. It should be noted that the selected numbers must be two digits and smaller equal to 44.Then the first 22 numbers that were selected are assigned to group A and the next 22 numbers to group B. On the other hand, the patients undergoing surgery are numbered from 1 to 44 from the beginning of the sampling process, and according to the numbers assigned to them, they are in the subgroup A and B are placed. For group A, intravenous ketorolac drug regimen is used along with diclofenac suppositories, and for group B, intravenous ketorolac drug regimen is used alone.

Blinding (investigator's opinion)
Double blinded

Blinding description
The meaning of double-blind is that neither the surgeon nor the patients will know about the randomization method and treatment protocol taken into consideration.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Tehran Islamic Azad University of Medical Sciences

Street address
No1, East Payambar Ave, Abazar Blvd, Tehran

City
Tehran

Province
Tehran

Postal code
1473673341

Approval date
2022-12-31, 1401/10/10

Ethics committee reference number
IR.IAU.TMU.REC.1401.282

Health conditions studied

1

Description of health condition studied
Pain reduction after abdominal surgery with general anesthesia

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Type of medicine, pain intensity, sex, age, type of surgery

Timepoint
Recovery, the first 6 hours and the first 12 hours after the operation

Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

intervention group: In this double-blind randomized clinical trial study, patients undergoing elective abdominal surgery with general anesthesia who are in anesthesia class 1 and 2 were interviewed before surgery and background information including gender, age, clinical and medication records were obtained from them. The question is recorded in the study checklist. After complete preparation, placement of intravenous line, monitoring and receiving oxygen for 3 to 5 minutes with premedication of midazolam 2 mg and fentanyl 2 cc and sodium thiopental 5 mg/kg and atracurium 0.5 mg/kg under anesthesia induction. They are placed and then anesthesia is administered with N2O gas and isoflurane oxygen and repetition of fentanyl and atracurium. At the end of the operation and randomly using a random table of numbers, the patients are evaluated in two groups. The first group receives diclofenac suppositories (100 mg each) and Ketorolac ampoules (15 mg) in the form of infusion. Patients will not know about the randomization method and the considered treatment protocol. Pain intensity is measured during the first 6 hours of recovery and the first 12 hours after the operation. In the group with moderate and severe pain, 10 and 20 mg of pethidine is injected, and the consumption of the two groups is compared.

Category

Treatment - Drugs

2

Description

intervention group: In this double-blind randomized clinical trial study, patients undergoing elective abdominal surgery with general anesthesia who are in anesthesia class 1 and 2 were interviewed before surgery and background information including gender, age, clinical and medication records were obtained from them. The question is recorded in the study checklist. After complete preparation, placement of intravenous line, monitoring and receiving oxygen for 3 to 5 minutes with premedication of midazolam 2 mg and fentanyl 2 cc and sodium thiopental 5 mg/kg and atracurium 0.5 mg/kg under anesthesia induction. They are placed and then anesthesia is administered with N2O gas and isoflurane oxygen and repetition of fentanyl and atracurium.At the end of the operation and randomly using a random table of numbers, the patients are evaluated in two groups. The second group receives only Ketorolak ampoules.Patients will not know about the randomization method and the considered treatment protocol. Pain intensity is measured during the first 6 hours of recovery and the first 12 hours after the operation. In the group with moderate and severe pain, 10 and 20 mg of pethidine is injected, and the consumption of the two groups is compared.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Amiralmomenin hospita

Full name of responsible person
Heydar Darvishi

Street address
Shirmohammadi Ave, Nazi abad, Tehran

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1811694784

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Email
Hdarvishi@iauimuic.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
Mehrdad Gholamzad

Street address
Goleyakh Ave, Shariati Ave, Tehran

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Tehran

Province
Tehran

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1949635881

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Int.affairs@tms.iau.ir

Grant name

Grant code / Reference number

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

Title of funding source
Islamic Azad University

Proportion provided by this source
100

Public or private sector
Private

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
Islamic Azad University

Full name of responsible person
Seyede zahra Seyf

Position
Medical student

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no further information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available