Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of pain after abdominal surgery in patients receiving ketorolac and nasocalcin spray or lidocaine and nasocalcin spray

Protocol summary

Study aim
Determination of pain level after abdominal surgery in patients receiving ketorolac and nasocalcin spray or lidocaine and nasocalcin spray in referral patients.

Design
A controlled, parallel-group, double-blind, randomized, phase 2 clinical trial on 58 patients. An online random number table was used for randomization.

Settings and conduct
The drugs were divided by the head of the surgery department as A/B:A(receiver of nasocalcin spray and Ketorolac ampoule intravenously)and B(recipient of nasocalcin spray and lidocaine ampoule intravenously).The doctor and the patient were not aware of which group the patient was in.Medicines were administered to the patients upon entering the operating room and in the recovery room The place of treatment was Bo Ali Hospital in Tehran.

Participants/Inclusion and exclusion criteria
Entry requirements: 15-75 years old Informed and written consent Non-use of drugs and alcohol Elective surgery Conditions of non-entry: reduced level of consciousness Hemodynamic disorder Abnormal bleeding during The operation lasts more than 4 hours

Intervention groups
Intervention:D(receiver of nasocalcin spray and ketorolac ampoule intravenously)control:placebo recipient(receiver of nasocalcin spray and lidocaine ampoule intravenously)before abdominal surgery

Main outcome variables
Postoperative pain score based on visual analog scale The amount of drug received during the first 24 hours

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230710058733N1**
Registration date: **2023-09-26, 1402/07/04**
Registration timing: **retrospective**

Last update: **2023-09-26, 1402/07/04**
Update count: **0**

Registration date
2023-09-26, 1402/07/04

Registrant information

Name
Mahdiya Qasemi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 2200 6660

Email address
mahdieh.ir72@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-09-20, 1400/06/29

Expected recruitment end date
2023-06-19, 1402/03/29

Actual recruitment start date
2023-06-19, 1402/03/29

Actual recruitment end date
2023-09-10, 1402/06/19

Trial completion date
2023-09-10, 1402/06/19

Scientific title
Comparison of pain after abdominal surgery in patients receiving ketorolac and nasocalcin spray or lidocaine and nasocalcin spray

Public title
Comparison of pain after abdominal surgery in patients

receiving ketorolac and nasocalcin spray or lidocaine and nasocalcin spray

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Being 15-75 years old Sign a personal consent form to enter the study American Society of Anesthesiologists 1-2 Non-use of drugs and alcohol Elective surgery

Exclusion criteria:

Decreased level of consciousness Hemodynamic disorder Abnormal intraoperative bleeding Length of operation more than 4 hours

Age

From **15 years** old to **75 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **59**

Actual sample size reached: **59**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, a list of all patients who were willing to participate in the study was first prepared, and after matching the patients who met the inclusion criteria, we assigned a number to each patient. We considered numbers 1 to 29 as group A and 30 to 59 as group B. So, using the online random number table, the patients were divided into two groups (A group receiving intravenous nasocalcin spray and Ketorolac ampoule and B group receiving intravenous nasocalcin spray and lidocaine ampoule).

Blinding (investigator's opinion)

Double blinded

Blinding description

This research is a double-blind clinical trial (in order to make this study double-blind, the drugs used for the patients at the beginning of the study are A/B by the supervisor of the surgery department so that the clinical caregiver and the participants do not know the type of drug received.

Placebo

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

Head Office of Islamic Azad University of Medical Sciences, Tehran, Ayene Boulevard, Nabsheh Giley Street, Amir Pabarja Street, Do Rahi Kolak, Dr. Shariati Street, Tehran

City

Tehran

Province

Tehran

Postal code

1916893813

Approval date

2022-08-15, 1401/05/24

Ethics committee reference number

IR.IAU.TMU.REC.1401.169

Health conditions studied

1

Description of health condition studied

Pain after abdominal surgery

ICD-10 code

T81.9

ICD-10 code description

Unspecified complication of procedure

Primary outcomes

1

Description

Pain

Timepoint

1 hour and 6, 12, 24 hours after the operation, the amount

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

The amount of narcotic (pethidine) received after the operation

Timepoint

After surgery

Method of measurement

Amount of drug used.

Intervention groups

1

Description

2 puffs of nasocalcin and Ketorolac 30 mg ampoules were received intravenously. After patients enter the operating room, patients under general anesthesia with the same drugs (propofol 2 mg per kg of patient weight or Nesdonal 5 mg per kg of patient weight, midazolam 0.01 mg per kg of patient weight, fentanyl 2 - 3 macros per kilogram of patient weight and atrocurium 0.5 mg per kilogram of patient weight for induction and for maintenance, 1-2% isoflurane and oxygen N2o (50/50) were used. For patients during surgery, 1 macro per Every kilogram of the patient's weight, fentanyl was repeated every hour, and then at the end of the surgery, the reverse muscle relaxant was performed by a mixture of neostigmine and atropine. Then, after the surgery and at 6, 12, 24 hours after the operation, the pain level of the patients was measured according to the pattern VAS was checked and in case of VAS>5, pethidine 30-50mg was injected intravenously to the patients and at the end of the first day, the amount of narcotic used was recorded in the questionnaire by a trained nurse.

Category

Prevention

2

Description

They received 2 puffs of nasocalcin spray and lidocaine ampoules intravenously, and after the patients entered the operating room, the patients were under general anesthesia with the same drugs (propofol 2 mg per kg of patient weight or Nesdonal 5 mg per kg of patient weight) , midazolam 0.01 mg per kg of patient weight, fentanyl 2-3 macros per kg of patient weight and atrocurium 0.5 mg per kg of patient weight for induction and for maintenance of isoflurane 1-2% and oxygen N2o (50/50)) was used. For patients during surgery, 1 macro per kilogram of the patient's weight of fentanyl was repeated every hour, and then at the end of the surgery, a reverse muscle relaxant was performed by a mixture of neostigmine and atropine. Then after the surgery and at 6 hours , 12,24, after the operation, the pain level of the patients was checked based on the VAS model, and in the case of VAS>5, pethidine 30-50 mg was injected intravenously to the patients, and at the end of the first day, the amount of narcotic used was recorded in a questionnaire by a trained nurse. It was registered.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Bu Ali Hospital

Full name of responsible person

Dr. Mahnaz Narimani Zamanabadi

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At the beginning of Damāvand Street, Imam Hossein Square, Tehran

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Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

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

Islamic Azad University

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

Islamic Azad University
Full name of responsible person
Dr. Mahnaz Narimani Zamanabadi
Position
student
Latest degree
Medical doctor
Other areas of specialty/work
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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