Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of pain after abdominal surgery in patients receiving Nasocalcin spray or vitamin D and Nasocalcin spray

Protocol summary

Study aim

Determining the amount of pain after abdominal surgery in patients receiving nasocalcin spray or vitamin D and nasocalcin spray in patients referred to the hospitals of Tehran Islamic Azad University of Medical Sciences in 2021

Design

A double-blind clinical trial, with parallel groups, randomized, phase 2 on 34 patients, for randomization, first a list of patients who were willing to participate in the research was prepared and after matching the individuals, we assigned a number to each patient and They were randomly placed in two groups according to the table of random numbers

Settings and conduct

The drugs were divided by the head of the surgery department as A/B (A received nasocalcin spray and distilled water intramuscularly and B received nasocalcin spray and vitamin D intramuscularly). The doctor and the patient were not aware of which group the patient was in. Medicines were prescribed to the patients when they entered the operating room and in the recovery room. The method of calculating the amount of medicine and spray puffs in the patients was as follows: weight less than or equal to 60 kg, one puff of nasocalcin spray Weight more than 60 kg, two puffs of Nasocalcin spray Two cc intramuscular distilled water Intramuscular Vitamin D Ampoule

Participants/Inclusion and exclusion criteria

Inclusion age15-75years Signing a personal and informed consent form to participate in the study ASA1and2 Non-use of drugs and alcohol Elective surgery Exclusion Loss of consciousness Hemodynamic disorder Abnormal intraoperative bleeding operation more than4hours

Intervention groups

Medicines were administered to the patients upon entering the operating room and in the recovery room.

Main outcome variables

Postoperative pain in recovery and 6, 12, 24 hours after the operation, the pain level of the patients was checked based on the VAS pattern

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230110057093N1**
Registration date: **2023-03-14, 1401/12/23**
Registration timing: **retrospective**

Last update: **2023-03-14, 1401/12/23**
Update count: **0**

Registration date

2023-03-14, 1401/12/23

Registrant information

Name
Fatemeh Karimi
Name of organization / entity
Country
Iran (Islamic Republic of)
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fatemehkarimi9673@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-21, 1401/01/01

Expected recruitment end date

2022-03-21, 1401/01/01

Actual recruitment start date

2022-03-21, 1401/01/01

Actual recruitment end date

2022-03-21, 1401/01/01

Trial completion date
2022-12-22, 1401/10/01

Scientific title
Comparison of pain after abdominal surgery in patients receiving Nasocalcin spray or vitamin D and Nasocalcin spray

Public title
Comparison of pain after abdominal surgery in patients receiving Nasocalcin spray or vitamin D and Nasocalcin spray

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:
Having an age between 15-75 years Signing a personal and informed consent form to participate in the study 12ASA No abuse of drugs and alcohol Elective surgery

Exclusion criteria:
Loss of consciousness Hemodynamic disorder Abnormal intraoperative bleeding length of the 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
- Data analyser

Sample size
Target sample size: **34**
Actual sample size reached: **34**

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 17 as group A and 18 to 34 as group B. Then, using an online random number table, the patients were placed in two groups (A group receiving nasocalcin spray and B group receiving vitamin D and nasocalcin spray).

Blinding (investigator's opinion)
Double blinded

Blinding description
In order to be double-blinded (patients and researchers did not know which patients were placed in which group), the drugs used for patients (nasocalcin spray or vitamin D and nasocalcin spray) at the beginning of the study by the head of the surgery department in two containers with the same appearance It was divided and named as A/B (A included nasocalcin spray and B included vitamin D and nasocalcin spray). Before the operation, drugs from one of the containers were randomly prescribed to the patient by the nurse of the surgery department and recorded in the data collection form by the relevant nurse.

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
Headquarters building of Tehran Islamic Azad University of Medical Sciences, corner of Gol Ikh St., Aineh Blvd., Amir Pabarja St., Doktor Shariati St., Doktor Shariati St., Tehran

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Approval date
2022-05-11, 1401/02/21

Ethics committee reference number
IR.IAU.TMU.REC.1401.061

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
In recovery and at 6, 12, 24 hours after the operation, the amount

Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
One group received nasocalcin spray and vitamin D injection intramuscularly. The method of calculating the amount of medicine and spray puffs in patients was as follows: • Weight less than or equal to 60 kg, one puff of nasocalcin spray • Weight greater than or equal to 60 kg, two puffs of nasocalcin spray • Intramuscular vitamin D ampoule

Category
Prevention

2

Description
One group received nasocalcin spray and distilled water intramuscularly. The way to calculate the amount of medicine and spray puffs in the patients was as follows: • weight less than or equal to 60 kg, one puff of nasocalcin spray • weight greater than or equal to 60 kg, two puffs of nasocalcin spray • • two cc of distilled water intramuscularly

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Bo Ali Hospital

Full name of responsible person
Mahnaz Narimani Zamanabadi

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Headquarters building of Tehran Islamic Azad University of Medical Sciences, corner of Gol Ikh St., Aineh Blvd., Amir Pabarja St., Doktor Shariati St., Doktor Shariati St., Tehran

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Recruitment center

Name of recruitment center
Amirul Mominin Hospital

Full name of responsible person
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Recruitment center

Name of recruitment center
Farhihtegan Hospital

Full name of responsible person
Mahnaz Narimani Zamanabadi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
Dr. Majid Naqipour

Street address
Headquarters building of Tehran Islamic Azad University of Medical Sciences, corner of Gol Ikh St., Aineh Blvd., Amir Pabarja St., Doktor Shariati St., Doktor Shariati St., Tehran

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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

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

Mahnaz Narimani Zamanabadi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Fatemeh Karimi

Position

student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

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Person responsible for updating data

Contact

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Latest degree

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Other areas of specialty/work

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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