Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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)

Phone

+98 21 8876 2481

Email address

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 12وASA 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
City
Tehran
Province
Tehran
Postal code
1949635881
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

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

City
Tehran

Province
Tehran

Postal code
1949635881

Phone
+98 21 2660 2642

Email
mahnaznarimani@gmail.com

2

Recruitment center

Name of recruitment center
Amirul Mominin Hospital

Full name of responsible person
Mahnaz Narimani Zamanabadi

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

City
Tehran

Province
Tehran

Postal code
1949635881

Phone
+98 21 2660 2642

Email
mahnaznarimani@gmail.com

3

Recruitment center

Name of recruitment center
Farhihtegan Hospital

Full name of responsible person
Mahnaz Narimani Zamanabadi

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

City
Tehran

Province
Tehran

Postal code
1949635881

Phone
+98 21 2660 2642

Email
mahnaznarimani@gmail.com

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

City
Tehran

Province
Tehran

Postal code
1949635881

Phone
+98 21 2660 2642

Email
mahnaznarimani@gmail.com

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

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

City
Tehran

Province
Tehran

Postal code
1949635881

Phone
+98 21 2660 2642

Email
mahnaznarimani@gmail.com

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

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

City
Tehran

Province
Tehran

Postal code
1949635881

Phone
+98 901 195 2320

Email
fatemehkarimi9673@gmail.com

Person responsible for updating data

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

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

City
Tehran

Province
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Postal code
1949635881

Phone
+98 21 2660 2642

Email
fatemehkarimi9673@gmail.com

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