Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation of the effect of topical sodium bicarbonate injection on pain after inguinal hernia surgery

Protocol summary

Study aim
determine of the effect of topical sodium bicarbonate injection on pain after inguinal hernia surgery

Design
Two arm parallel group randomised trial with blinded postoperative care and outcome assessment design of 100 patient.The rand function of Excel software was used for randomization.

Settings and conduct
In the participating patients of this study (Imam Ali Hospital and Shahid Madani Hospital in Karaj), all surgeries will be performed by a single surgeon and an anesthesiologist. The surgery will be done under general anesthesia with a classic incision. After repairing the defect and placing the mesh for the inguinal hernia, the surgical site will be irrigated with a solution (drug/placebo) once. Then, the patients' pain will be measured 12 and 24 hours after the operation. The study is double-blind (both the evaluator and the patient), the preparation of the solution is done by another person, and patients will be introduced to the evaluator with a code.

Participants/Inclusion and exclusion criteria
Participants: Candidate patients for inguinal hernia repair surgery / Entry conditions: indirect inguinal hernia, informed consent of patient, not recurrence inguinal hernia / Conditions of non-entry: psychopathy, drug addiction, chronic use of Analgesics, sensory and motor disorders, complications of strangulation and gangrene, loss of consciousness, patients with acute problems and needing emergency surgeries, recurrent inguinal hernia.

Intervention groups
In the participants of this study, the surgery will be performed under general anesthesia using a classic incision. After repairing the defect and placing the mesh for the inguinal hernia, the surgical site will be irrigated once with a solution (Intervention group: Sodium bicarbonate or control group: Normal saline) and then stitched up.

Main outcome variables
The patient's pain score is based on Visual Analogue Scale (VAS)

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20240928063193N1**
Registration date: **2024-10-24, 1403/08/03**
Registration timing: **prospective**

Last update: **2024-10-24, 1403/08/03**
Update count: **0**

Registration date
2024-10-24, 1403/08/03

Registrant information
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-11-20, 1403/08/30
Expected recruitment end date
2025-03-10, 1403/12/20
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of topical sodium bicarbonate injection on pain after inguinal hernia surgery

Public title

Evaluation of the effect of topical sodium bicarbonate injection on pain after inguinal hernia surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

indirect inguinal hernia informed consent of patient not recurrence inguinal hernia

Exclusion criteria:

psychopathy Drug addiction Chronic use of Analgesics Sensory and motor disorders Complications of strangulation and gangrene loss of consciousness Patients with acute problems and needing emergency surgeries recurrent inguinal hernia

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization method will be used for sampling. The length of the block for each of the treatment groups is considered to be 4, which means that each block will include two people from the intervention group and two people from the comparison group. If we show the people of the intervention group with the letter A and the people of the comparison group with the letter B, in this case according to the formula n!/r!(n!_r!) We will have 6 combinations of four in the form of (AA,BB), (AB, BA), (BA, BA), (BA, BA), (BB, AA), and (AB, BA). Then random codes will be generated for each of these blocks. Then one of these blocks will be randomly selected and based on the sequence of letters A and B in the selected block, eligible people will be assigned to treatment or comparison groups. This random process of selecting blocks and assigning people to the intervention and comparison groups will continue until the desired sample size is reached. This method solves the problem of imbalance that can occur in simple randomization. To ensure the blinding of patients and assessors, each of these blocks will be identified with a code. On the other hand, the injection of normal saline containing sodium bicarbonate (intervention) and normal saline without sodium bicarbonate (placebo) will be done in the same amounts and using the same syringes.

Blinding (investigator's opinion)

Double blinded

Blinding description

The purpose of blinding, depending on its type, is not to inform the patients and the investigator about the outcome of assigning people to treatment groups. In such studies, patients should not know which group they belong to.This point is very important, especially when a type of subjective measurement such as pain (result of this study) is involved. Therefore, this study was designed as a double blind. In this way, the evaluator and the subject (patients) are not aware of the status of assigning people to the study groups. For the study subjects, the procedure is explained before random assignment and receives one of the two treatments randomly And the medicine used for people is not known in advance, On the other hand, the injection of normal saline containing sodium bicarbonate (intervention) and normal saline without sodium bicarbonate (placebo) will be done in the same amounts and using the same syringes to irrigate the surgical field. in such a way that it is not possible for the patient to distinguish them from each other, Therefore, the patient will be unaware of which group she is in. The evaluator and the patient will not be aware of the patients belonging to the treatment groups. The process of sampling and preparing the material for spraying (Irrigate) is done by another person.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Alborz University of Medical Sciences

Street address

Deputy of Research and Technology .,saffarian Ave., 45 Metri of Golshahr ., Karaj

City

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Province

Alborz

Postal code

3198764653

Approval date

2024-09-28, 1403/07/07

Ethics committee reference number

IR.ABZUMS.REC.1403.145

Health conditions studied

1

Description of health condition studied
Unilateral indirect inguinal hernia, without obstruction or gangrene, recurrent
ICD-10 code
K40.91
ICD-10 code description
Unilateral inguinal hernia, without obstruction or gangrene, recurrent

Primary outcomes

1

Description
The patient's pain score is based on Visual Analogue Scale (VAS)
Timepoint
12 and 24 hours after surgery
Method of measurement
Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description
In the intervention group (50 patients), a 30-minute session will be held to explain the study's objectives and the intervention process to obtain informed consent. The duration for which the patient will be involved in the study will be from the consent session (upon admission) until 24 hours after the surgery. During the surgery, after sterilizing the incision site and making the classic incision and repairing the defect, an inguinal hernia will be fixed using the Lichtenstein method: (this is a type of tension-free repair where a synthetic mesh (11x6 Proline mesh from Asia Surgical Company) is used to reconstruct the floor, and the mesh is placed in front of the transversalis fascia.) After placing the mesh, before closing the fascia, the surgical site will be irrigated once with 5 milliliters of diluted sodium bicarbonate solution at 7.5% (1 ml of 7.5% sodium bicarbonate diluted with 4 ml of normal saline). The source for this solution is a 50-milliliter vial of 7.5% sodium bicarbonate ($NaHCO_3$) from Samen Pharmaceutical Company and a 100-milliliter bag of 0.9% sodium chloride (NaCl) from the samen company. After the surgery, all study patients will receive standard pain management as follows:1) Intravenous acetaminophen 1 gram every 8 hours2) Intravenous morphine 5 milligrams every 12 hours
Category
Treatment - Drugs

2

Description
Control group: In the control group (50 patients), a 30-minute session is held to explain the study's objectives and the intervention method to obtain consent. The duration of the patient’s participation in the study will be from the consent session (before hospitalization) until 24 hours after the surgical procedure. During the surgical operation, after sterilizing the incision site and making the classical incision, the inguinal hernia repair is performed using the Lichtenstein method: (a type of tension-free repair where synthetic tissue (11x6 polypropylene mesh made by Asia Surgical Company) is used to reconstruct the floor and is placed in front of the transversalis fascia.) After placing the mesh, before closing the fascia, the surgical site is irrigated with 5 milliliters of normal saline solution once. The source of the solution is a 100 milliliter vial of 0.9 percent sodium chloride (NaCl) from Samen Pharmaceutical Company. After the surgery, all study patients will receive standard pain management as follows:1) Intravenous acetaminophen 1 gram every 8 hours2) Intravenous morphine 5 milligrams every 12 hours
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
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Full name of responsible person
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2

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

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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
Karaj 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
Karaj University of Medical Sciences
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Ali Rahmati
Position
Medical Intern
Latest degree
A Level or less
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