

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 2026

Comparison of the effect of Subdiaphragmatic Saline and sodium-bicarbonate Irrigation for Reducing Postoperative Shoulder Pain after Laparoscopic hysterctomy Surgeries

Protocol summary

Study aim

Comparison of the effect of sub-diaphragmatic injection of sodium bicarbonate with normal saline on shoulder pain

Design

The clinical trial has a control group with parallel groups of 2 treatment groups, double-blind, and randomized, 90 patients and a control group based on block randomization.

Settings and conduct

After the injection of sodium bicarbonate and normal saline at the end of the operation, the presence and intensity of shoulder pain will be measured and recorded based on the VAS visual pain scale during recovery and at 12, 24 and 48 hours after surgery. If there is pain Shoulders with VAS greater than or equal to 4 and additional painkillers including diclofenac suppositories were given to the patients and finally the amount of additional painkillers received to improve shoulder pain within 24 hours after the operation will be recorded in the patients. And 3 groups will be compared with each other.

Participants/Inclusion and exclusion criteria

Elective laparoscopic hysterectomy surgery,ASA 1 and 2, absence of allergy to sodium bicarbonate, liver and kidney dysfunction, heart disease, shoulder pain or myofascial pain, absence of cognitive impairment

Intervention groups

In the first group (saline group): during surgery, 500 cc of normal saline under the right hemodiaphragm before The removal of carbon dioxide . In the second group (sodium bicarbonate group), 50 cc of bicarbonate Sodium 7.9% in 500 cc of normal saline 0.9% at the end of the surgery to the same.And in the control group (group 3) no intervention will be done.

Main outcome variables

shoulder pain and the amount of receiving additional

painkillers

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220409054465N2**

Registration date: **2024-02-04, 1402/11/15**

Registration timing: **registered_while_recruiting**

Last update: **2024-02-04, 1402/11/15**

Update count: **0**

Registration date

2024-02-04, 1402/11/15

Registrant information

Name

Lida Grrosi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3344 3164

Email address

lgarrosi@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-02-04, 1402/11/15

Expected recruitment end date

2024-04-20, 1403/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Subdiaphragmatic Saline and sodium- bicarbonate Irrigation for Reducing Postoperative Shoulder Pain after Laparoscopic hysterectomy Surgeries

Public title

Comparison of the effect of Subdiaphragmatic Saline and sodium- bicarbonate Irrigation for Reducing Postoperative Shoulder Pain after Laparoscopic hysterectomy Surgeries

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Elective laparoscopic hysterectomy surgery Age 20 to 60 years ASA (anesthesia class) 1 and 2 No allergy to sodium bicarbonate Absence of liver and kidney dysfunction Absence of heart disease Absence of previous shoulder pain or myofascial pain Absence of cognitive impairment

Exclusion criteria:

Unwillingness to participate in the study Cancer of the uterus and ovaries With severe intra-abdominal adhesions History of underlying diseases (stroke, cerebral thrombosis, chronic hypertension, liver and kidney diseases)

Age

From **20 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

All patients undergo laparoscopic hysterectomy by a team of surgeons. And the intervention will be done based on the block randomization list by the operating room technician, and after random assignment, the patients will be divided into 3 groups. Randomization in this study is done in the form of block randomization. Randomly permuted blocks (block size of 3) will be generated using the website www.sealedenvelope.com and will be written on the drug envelopes. After receiving the consent form and after confirming the eligibility of the patient, the random code will be randomized based on the randomization sheet by the main researcher and based on a predetermined randomization plan in the ratio of 1:1:1 to receive drug or serum or control. and receive their corresponding intervention box. This

number was considered as the participant's randomization code and will be identified with this number until the end of the study. Randomization using closed envelopes based on the type of medicine is given to the operating room technician and then the patients are followed up.

Blinding (investigator's opinion)

Double blinded

Blinding description

After obtaining informed consent from the patient to participate in the study, the patient will not know the type of intervention he received. In order to hide the random allocation process, the sequence of treatments will be written on the cards in order, then the cards will be placed in sealed envelopes. A 10-digit random code will be written on each envelope without any order or frame, which is the identification number of the relevant patient, and only one of the executive agents of the project, who will not be involved in the evaluation, analysis and interpretation of the results, will be aware of the relevant code. When another doctor (clinical caregiver) declares the eligibility of a patient, the nurse provides the envelope to the doctor and the desired surgical intervention will be performed based on the type mentioned in the envelope. And the results of the study will be checked by a outcome assessor who is unaware of the type of intervention. Due to the anesthesia during the surgery, the patients will not know the type of intervention. The statistics analyzer and the researcher will not be aware of the type of medicine used.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Tehran university of Medical science

Street address

Qods street, Keshavarz boulevard

City

Tehran

Province

Tehran

Postal code

1417653761

Approval date

2023-10-30, 1402/08/08

Ethics committee reference number

IR.TUMS.MEDICINE.REC.1402.393

Health conditions studied

1

Description of health condition studied

Reduction of shoulder pain after laparoscopic surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Shoulder pain

Timepoint

12,24,48 hours after surgery

Method of measurement

VAS questionnaire

2

Description

Extra sedative

Timepoint

12,24,48 hours after surgery

Method of measurement

number of requested sedative

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: In the first group (saline group): during normal surgery, 500 cc of saline is sprayed under the right hemodiaphragm before removing carbon dioxide.

Category

Treatment - Surgery

2

Description

Intervention group2: In the second group (sodium bicarbonate group), 50 cc of 7.9% sodium bicarbonate (factory and country of manufacture) in 500 cc of 0.9% normal saline will be sprayed at the end of the surgery in the same way as the saline group

Category

Treatment - Surgery

3

Description

In the control group (group 3), no intervention will be performed. At the end of the procedure, the patient is supine and the gas is released slowly.

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Arash hospital

Full name of responsible person

Lida Garrosi

Street address

Resalat H, Trehranpars, Rashid Av, Arash hospital

City

Tehran

Province

Tehran

Postal code

1653915981

Phone

+98 21 7771 9922

Email

lida.garrosi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraian

Street address

Qods street, keshavarz boulevard

City

Tehran

Province

Tehran

Postal code

147653761

Phone

+98 21 6649 2271

Email

vcr@sina.tums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Tehran 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

9922 7771 21 98+

Email

lgarrosi@zums.ac.ir

Person responsible for general inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Lida Garrosi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Tehranpars street , Baghdarnia ave, Arash hospital

City

Tehran

Province

Tehran

Postal code

1653915981

Phone

9922 7771 21 98+

Email

Lgarrosi@zums.ac.ir

Person responsible for updating data**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Lida Garrosi

Position

Non-faculty specialist doctor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

tehranpars, Rashid BLV, Arash Hospital

City

Tehran

Province

Tehran

Postal code

1653915981

Phone

9922 7771 21 98+

Email

Lgarrosi@zums.ac.ir

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Lida garrosi

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Tehranpars, Rashid BLV, Arash Hospital

City

Tehran

Province

Tehran

Postal code

1653915981

Phone**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