Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 May 2026

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

Public title
Comparision of the effect of Subdiaphragmatic Saline and sodium- bicharbonate Irrigation for Reducing Postoperative Shoulder Pain after Laparoscopic hysterctomy 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

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 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
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

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