Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

Investigation of oral Tizanidine on postoperative shoulder pain in laparoscopic cholecystectomy compared to the control group

Protocol summary

Study aim
Determining the effect of oral tizanidine on shoulder pain after laparoscopic cholecystectomy

Design
Clinical trial with a control group, with parallel groups, double-blind, randomized, phase 3 on 50 patients. The rand function of Excel software will be used for randomization.

Settings and conduct
This study will be conducted on patients at Aria Hospital in Mashhad in 2023The patients will be randomly divided into two groups with the help of a random number table. The patients will know about participating in the study, but they will not be aware of the drugs in groups A and B. The evaluators will not be aware of the contents of the groups. Before the operation, all patients will be informed about the use of the analog vision scale. (VAS) will be explained. The assessment of shoulder pain in patients will be based on a 10-point visual analog scale, so that the number 10 represents the worst (most severe) pain experienced by the patient and the number 0 represents no pain at the site. Patients are checked for pain at 2, 4, and 24 hours after surgery. The need for additional painkillers, which is the amount of opioid injections received (5 mg of morphine per injection), will also be calculated.

Participants/Inclusion and exclusion criteria
entry criteria:1- Patients undergoing elective laparoscopic cerebrocystectomy 2- Age between 18 and 65 years Non-entry criteria:1- People with contraindications to tizanidine prescription 2- Converting laparoscopic surgery to open surgery 3-Using opium

Intervention groups
Intervention group: Patients will receive 4 mg of tizanidine orally dissolved in 50 ml of water 2 hours before anesthesia. Placebo group: They will receive 50 ml of pure water, which will be identical to the original drug in terms of appearance.

Main outcome variables
Dose of painkillers received; side effects of tizanidine;

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230726058933N1**
Registration date: **2023-09-05, 1402/06/14**
Registration timing: **prospective**

Last update: **2023-09-05, 1402/06/14**
Update count: **0**

Registration date
2023-09-05, 1402/06/14

Registrant information

Name
Amirhossein Khorasani

Name of organization / entity
Mashhad Medical Science Islamic Azad University

Country
Iran (Islamic Republic of)

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+98 51 3726 6543

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-09-23, 1402/07/01

Expected recruitment end date
2024-09-22, 1403/07/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigation of oral Tizanidine on postoperative shoulder pain in laparoscopic cholecystectomy compared to the control group

Public title
Investigating the effect of oral tizanidine on shoulder pain

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Patients who undergo elective laparoscopic cholecystectomy surgery will be included in the study Patients must be between 18 and 65 years old

Exclusion criteria:
Patients whose surgery was changed from laparoscopy to laparotomy Patients who are allergic to tizanidine Patients who take opium

Age
From **18 years** old to **65 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description
Qualified participants will be randomly divided into control and treatment groups, and the individuals who refer will be divided using random numbers generated by the computer. In this way, on the Google randomization site To the address: https://www.google.com/search?q=random+number , the number will be between 1 and 2 clicks. If 1 patient is assigned to the treatment group and 2 patients are assigned to the control group, this study follows a double-blind design, in which the participants and the research team involved in data collection, analysis, and interpretation compared to The treatment allocations will be blind to the control group, a drug that will be completely similar to the main drug will be injected into the patients, and the information of both groups will be available to the research team as data A and B. Blinding during the study to minimize bias and ensure The integrity of the results will be maintained.

Blinding (investigator's opinion)
Double blinded

Blinding description
In this double-blind research, the patients will be informed about participating in a study plan before the surgery, and it will be explained to the patients that they will be placed in two groups, but they will not be informed about being placed in the intervention and placebo groups, and they will be divided into groups A and B. The evaluators will also There are people who have not observed the patients before the operation, during the operation and during the drug injection, and then they complete the necessary checklists by being present at the bedside of patients of groups A and B.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Medical Faculty of Islamic Azad University - Mashhad Medical Sciences Unit

Street address
14 Imam Khomeini-Imam Khomeini Street (Sarab Alley) - Dr. Mohammad Shahin Far Medical Faculty

City
Mashhad

Province
Razavi Khorasan

Postal code
9187147578

Approval date
2023-06-28, 1402/04/07

Ethics committee reference number
IR.IAU.MSHD.REC.1402.031

Health conditions studied

1

Description of health condition studied
Shoulder pain after laparoscopic cystectomy

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Shoulder pain

Timepoint
2, 4 and 24 hours after surgery

Method of measurement
visual analogue scale

2

Description
Dose of painkillers received
Timepoint
With each injection in case of pain
Method of measurement
Number of injections

3

Description
Side effects of tizanidine
Timepoint
2, 4 and 24 hours after surgery
Method of measurement
Ask the patient

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 2 hours before general anesthesia for surgery, the patients will receive one dose of Tizanidine, prepared by Actoverco (Actoverco) under the brand name Tizanover, one capsule of 4 mg will be dissolved in 50 ml of water and will be given to the patients.
Category
Treatment - Drugs

2

Description
Control group: They will receive the placebo in the form of 50 ml of pure water, which will be the same as the original drug in terms of appearance.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Aria hospital
Full name of responsible person
Hamed Beyzaii
Street address
Mashhad - Golestan Street - Golestan Sharghi 5
City
Mashhad
Province
Razavi Khorasan
Postal code
9513633938
Phone
+98 51 3222 9094
Email
info@aria-hospital.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Islamic Azad University
Full name of responsible person
Faride Namvar
Street address
Mashhad . Imam Reza Hospital Square, Chamran Street, Chamran15. Mashhad Islamic Azad University of Medical Sciences
City
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Province
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9185634351
Phone
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Email
info@iaumshms.ac.ir
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
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
Islamic Azad University
Full name of responsible person
Hamed Beyzaii
Position
Consultant
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is 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
Yes - There is 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
Title and more details about the data/document
Patient data after de-identification
When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available
For all people
Under which criteria data/document could be used
In case of coordination with the main person in charge, the use of data will be allowed
From where data/document is obtainable
The main person responsible for the project: Dr. Hamed Beyzaii hmd_beyzaii@yahoo.com-09153106236
What processes are involved for a request to access data/document
In case of submitting an official request by email or message on authorized virtual networks, a response will be given within ten working days.
Comments