Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Investigating the Efficacy of Local Injection of Ropivacaine on Postoperative Pain in Patients Undergoing Kocher's Incision: A Randomized Clinical Trial

Protocol summary

Study aim
To evaluate the efficacy of local ropivacaine injection at the surgical incision site in reducing postoperative pain in patients undergoing surgery with Kocher's incision.

Design
Randomised, parallel group, double-blind, controlled clinical trial, phase 3, conducted on 48 patients.

Settings and conduct
The study will be conducted in Madani Hospital. Eligible patients will be randomly assigned to two groups after obtaining informed consent. Drug injection will be performed by the surgeon without the knowledge of the patient or the data collector. Double-blind design is maintained.

Participants/Inclusion and exclusion criteria
Participants aged 18 to 65 years with a body weight between 45 and 100 kg, ASA class I or II, and candidates for Kocher’s incision surgery will be included; patients with known allergy to local anesthetics, severe cardiovascular, renal, or hepatic disease, history of substance abuse, or ASA class greater than II will be excluded.

Intervention groups
The intervention group will receive 20 mL of 5 mg/mL ropivacaine subcutaneously at the Kocher’s incision site at the end of surgery. The control group will receive 20 mL of 0.9% normal saline in the same manner.

Main outcome variables
Postoperative pain score measured by VAS at 2, 4, 8, 12, and 24 hours after surgery; time to first rescue analgesic administration; total dose of rescue analgesics within 24 hours.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250731066712N1**
Registration date: **2025-08-03, 1404/05/12**
Registration timing: **prospective**

Last update: **2025-08-03, 1404/05/12**
Update count: **0**

Registration date
2025-08-03, 1404/05/12

Registrant information
Name
Nastaran Hossein shiroudi
Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-08-11, 1404/05/20

Expected recruitment end date
2025-10-22, 1404/07/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Investigating the Efficacy of Local Injection of Ropivacaine on Postoperative Pain in Patients

Undergoing Kocher's Incision: A Randomized Clinical Trial

Public title
Local Ropivacaine Injection for Postoperative Pain Reduction in Patients Undergoing Kocher's Incision

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Indication for surgery with Kocher’s incision Signed informed consent ASA class I–II Age 18 to 65 years Weight between 45 and 100 kg No known allergy to local anesthetics No severe cardiovascular, renal, or hepatic comorbidities

Exclusion criteria:
Allergy to local anesthetics Patient’s refusal to continue participation at any stage Unexpected complications during surgery Conversion to laparoscopic or other surgical approaches

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

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **48**

Randomization (investigator's opinion)
Randomized

Randomization description
A block randomization method with a block size of 4 and a 1:1 allocation ratio was used to assign participants to either the intervention (ropivacaine) or control (normal saline) group. The randomization list was generated using Random Allocation Software by an independent statistician who was not involved in the recruitment, intervention, or outcome assessment. To ensure balanced group sizes over time, random permutations of block sequences (e.g., AABB, ABAB, BBAA, etc.) were used. Each allocation code was sealed in an opaque, sealed, and sequentially numbered envelope. These envelopes were prepared by a third party blinded to the study objectives and group assignments. Upon enrollment and informed consent, the operating room nurse opened the next envelope in sequence to determine the assigned intervention, which was then administered accordingly.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study was conducted in a double-blind manner, meaning that both the patients and the outcome assessor were blinded to group allocation. Ropivacaine and placebo (0.9% normal saline) solutions were indistinguishable in volume, color, and appearance. The study medications were prepared in identical, unlabeled syringes by a third party not involved in the trial. Each syringe was marked with a code and administered by an anesthetic nurse or operating room staff unaware of the allocation at the end of the procedure. Postoperative pain assessment was performed by a nurse blinded to the treatment group. Group assignments were concealed until data analysis was complete.

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
Mahan boulevard, Madani square, Madani Hospital

City
Karaj

Province
Alborz

Postal code
3143744693

Approval date
2025-07-13, 1404/04/22

Ethics committee reference number
IR.ABZUMS.REC.1404.112

Health conditions studied

1

Description of health condition studied
Postoperative pain, Kocher’s incision, local ropivacaine infiltration, postoperative pain management

ICD-10 code
K80-K87

ICD-10 code description
Disorders of gallbladder, biliary tract and pancreas

Primary outcomes

1

Description
Postoperative pain intensity at the surgical incision site

Timepoint
Measurement of pain intensity at the surgical incision site at 2, 6, 12, and 24 hours after surgery

Method of measurement
Measurement of pain intensity using the Visual Analogue Scale (pain ruler)

Secondary outcomes

1

Description
Amount of analgesic medication used after surgery
Timepoint
Amount of analgesic medication used during the first 24 hours after surgery
Method of measurement
Calculation of the total milligrams of analgesic medication administered orally or intravenously, extracted from the patient's medical records

Intervention groups

1

Description
Control group: At the end of surgery, patients in the control group will receive a subcutaneous injection of 20 mL of 0.9% normal saline in the same manner. The injection will be administered around the Kocher's incision site, with 10 mL injected along the upper edge and 10 mL along the lower edge of the incision.
Category
Treatment - Drugs

2

Description
Intervention group: At the end of surgery, patients in the intervention group will receive a subcutaneous injection of 20 mL of ropivacaine solution at a concentration of 5 mg/mL, diluted to 20 mL. The injection will be administered evenly around the Kocher's incision site, with 10 mL injected along the upper edge and 10 mL along the lower edge of the incision.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Madani Hospital
Full name of responsible person
Nastaran Hossein Shiroudi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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
Full name of responsible person
Nastaran Hossein Shiroudi
Position
resident
Latest degree
Medical doctor
Other areas of specialty/work
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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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

All potential data can be shared after de-identifying individuals.

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

Only for researchers working in academic and scientific institutions

Under which criteria data/document could be used

The use of documents for research and scientific work is allowed.

From where data/document is obtainable

Applicants should contact the following email to use and receive documents: nastaran.h.shiroudi@gmail.com

What processes are involved for a request to access data/document

In a period of less than two weeks, the applicants for receiving the documents who contacted by e-mail will be answered and the documents will be provided to them.

Comments