

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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

Country

Iran (Islamic Republic of)

Phone

+98 912 008 3995

Email address

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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

Street address

Mahan boulevard, Madani Square, Madani Hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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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