

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

nastaran.h.shiroudi@gmail.com

#### 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

##### City

Karaj

##### Province

Alborz

##### Postal code

3143744693

##### Phone

+98 26 3442 7001

##### Email

nastaran.h.shiroudi@gmail.com

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Karaj University of Medical Sciences

##### Full name of responsible person

Mohammad Hadi Bahri

##### Street address

Mahan boulevard, Madani square, Madani hospital

##### City

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##### Province

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3143744693

##### Phone

+98 26 3442 7001

##### Email

mh.bahri.fv@gmail.com

#### 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

General Surgery

##### Street address

Mahan boulevard, Madani square, Madani Hospital

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## Person responsible for scientific inquiries

**Contact**

**Name of organization / entity**

Karaj University of Medical Sciences

**Full name of responsible person**

Mohammad Hadi Bahri

**Position**

assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

General Surgery

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## Person responsible for updating data

**Contact**

**Name of organization / entity**

Karaj University of Medical Sciences

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Nastarn Hossein Shiroudi

**Position**

resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

General Surgery

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**Email**

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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**