

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of direct injection of Ropivacaine around the hip joint with pericapsular nerve group block (PENG) on opium consumption around the operation in patients undergoing Total hip Arthroplasty

#### Protocol summary

##### Study aim

Measuring the postoperative pain and opioid use in periarticular injection (PENG and direct) after total hip arthroplasty.

##### Design

A clinical trial with 2 groups, with parallel groups, double-blind, randomized, phase 3 on 128 patients. For randomization, a simple randomization method is used

##### Settings and conduct

After the approval of the ethics committee and obtaining the consent of the patients, 128 candidates for hip arthroplasty surgery at Imam Hossein Hospital who meet the entry criteria will be included in the study. Patients are assigned to one of the two groups by simple randomization. Individuals responsible for randomization from the research team will not be responsible for examining the dependent variable. The data analyst will not know about the coding of the groups.

##### Participants/Inclusion and exclusion criteria

Candidate for total hip arthroplasty No history of pelvic surgery No history of drug abuse and other psychoactive substances No history of psychiatric disease No allergy to local anesthetics Unwillingness to participate in the study

##### Intervention groups

Ultrasound group: The method of inducing analgesia will be the PENG method, in which 20 ml of 0.25% ropivacaine will be injected laterally to medially with a standard 100 mm, 22-gauge needle at the level between the tendon of the psoas muscle and the ramus pubis. Intervention group: 20 cc of 0.25% ropivacaine will be used and injected as a 5 ml injection into the ligamentum teres before stem placement, a five ml injection into the labrum after stem placement, and the remaining ten ml injection after capsular repair (5 ml into the capsule, 5 ml into the muscle).

##### Main outcome variables

Visual analog score

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230204057318N7**

Registration date: **2024-12-17, 1403/09/27**

Registration timing: **prospective**

Last update: **2024-12-17, 1403/09/27**

Update count: **0**

##### Registration date

2024-12-17, 1403/09/27

##### Registrant information

##### Name

Alireza Shakeri

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 7343 0000

##### Email address

dr.alirezashakeri@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2024-12-21, 1403/10/01

##### Expected recruitment end date

2025-04-20, 1404/01/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

## Trial completion date

empty

## Scientific title

Comparison of direct injection of Ropivacaine around the hip joint with pericapsular nerve group block (PENG) on opium consumption around the operation in patients undergoing Total hip Arthroplasty

## Public title

Comparison of direct injection and PENG

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Candidate for total hip arthroplasty

### Exclusion criteria:

No history of pelvic surgery No history of drug abuse and other psychoactive substances No history of psychiatric disease No allergy to local anesthetics Unwillingness to participate in the study

## Age

From **50 years** old to **75 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

## Sample size

Target sample size: **128**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Creating a random sequence using a simple randomization method using 120 cards (60 cards for each group) that are placed inside opaque sealed envelopes and will be shuffled by the patients before choosing.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

The patients and the person responsible for data collection and the person analyzing will be unaware of the coding. Only the anesthesiologist and orthopedic surgeon will be aware of the patient's group during surgery and will perform coding for each group.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Research Ethics Committees of School of Medicine - Shahid Beheshti University of Medical Sciences

##### Street address

Yaman st., Shahid Chamran Hwy.

##### City

Tehran

##### Province

Tehran

##### Postal code

1985717443

#### Approval date

2024-12-03, 1403/09/13

#### Ethics committee reference number

IR.SBMU.MSP.REC.1403.528

## Health conditions studied

### 1

#### Description of health condition studied

Pericapsular nerve group block

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Pain

#### Timepoint

At the times of entry to post-anesthesia care unit, 2, 6, 12, and 24 hours

#### Method of measurement

Visual Analogue Scale (VAS)

## Secondary outcomes

### 1

#### Description

Total postoperative opioid consumption in 24h

#### Timepoint

After 24h

#### Method of measurement

Consumption volume of patient controlled analgesia (PCA) pump

## Intervention groups

### 1

#### Description

Intervention group: The method of inducing analgesia will be the PENG method, in which 20 ml of 0.25%

ropivacaine will be injected laterally to medially with a standard 100 mm, 22-gauge needle at the level between the tendon of the psoas muscle and the ramus pubis.

**Category**

Treatment - Surgery

**2****Description**

Intervention group: 20 cc of 0.25% ropivacaine will be used and injected as a 5 ml injection into the ligamentum teres before stem placement, a five ml injection into the labrum after stem placement, and the remaining ten ml injection after capsular repair (5 ml into the capsule, 5 ml into the muscle).

**Category**

Treatment - Surgery

**Recruitment centers****1****Recruitment center****Name of recruitment center**

Imam Hossein Hospital

**Full name of responsible person**

Alireza Shakeri

**Street address**

Shahid Madani st, Imam ali Hwy.

**City**

Tehran

**Province**

Tehran

**Postal code**

1617763141

**Phone**

+98 21 7343 0000

**Email**

dr.alirezashakeri@gmail.com

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Afshin Zarghi

**Street address**

Shahid Beheshti University of Medical Sciences, Next to Taleghani Hospital, Yemen Street, Shahid Chamran Highway, Tehran, Iran

**City**

Tehran

**Province**

Tehran

**Postal code**

1983963113

**Phone**

+98 21 2243 9331

**Email**

zarghi@sbmu.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Shahid Beheshti 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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Alireza Shakeri

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Imam Hossein Hospital, Shahid Madani st.

**City**

Tehran

**Province**

Tehran

**Postal code**

1617763141

**Phone**

+98 21 7343 0000

**Fax****Email**

dr.alirezashakeri@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Alireza Shakeri

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Imam Hossein Hospital, Shahid Madani st.

**City**

Tehran

**Province**

Tehran

**Postal code**

1617763141

**Phone**

+98 21 7343 0000

**Fax**

**Email**

dr.alirezashakeri@gmail.com

Tehran

**Postal code**

1617763141

**Phone**

+98 21 7343 0000

**Fax**

**Email**

dr.alirezashakeri@gmail.com

## Person responsible for updating data

**Contact**

**Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Alireza Shakeri

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

**Street address**

Imam Hossein Hospital, Shahid Madani st.

**City**

Tehran

**Province**

## 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