Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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.

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Tehran

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1617763141

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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

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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

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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