

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

The effect of preoperative ultrasound-guided femoral block on post-operative pain management in hip replacement surgery compare with postoperative intra venous morphine administration

Protocol summary

Study aim

The effect of preoperative ultrasound-guided femoral block on post-operative pain management in hip replacement surgery compare with postoperative intra venous morphine administration

Design

Randomized control trial with parallel group phase 3 on 60 patients, randomized by block randomization from randomization .com site

Settings and conduct

This study will be done in Emam Reza hospital of Mashhad and patients with hip fracture who needs replacement therapy divided in two groups by randomization. In case group the patients undergo a femoral block and both groups undergo general anesthesia for replacement surgery; pain will be evaluate by NRS scale 1 hour after entering to the recovery and then every 4 hours for the next 12 hours and the day after the surgery. In the case of NRS more than 3, 0.5 mg /kg Morphine will be prescribed intravenously for both groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: patients with hip fracture and need to hip replacement therapy; age: 40 to 80 years old.
Exclusion criteria: any kind of neurologic disease; history of consuming of opioids or antipsychotic drugs and hypersensitivity to anesthesia or local anesthetic drugs.

Intervention groups

Patients in intervention group undergo a femoral block. After preparing of the groin region femoral nerve will be find by ultrasound linear probe and will be approached by nerve stimulator needle and after observing quadriceps contracture by 0.5 milliampere stimulation; 5 ml 2 percent Lidocaine with 5 ml 0.5percent Bupivacaine and 50 microgram fentanyl will be injected. No intervention are supposed to do for control group. Both groups undergoes general anesthesia for replacement

surgery.

Main outcome variables

Pain intensity with NRS scale

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150826023772N2**

Registration date: **2021-02-13, 1399/11/25**

Registration timing: **prospective**

Last update: **2021-02-13, 1399/11/25**

Update count: **0**

Registration date

2021-02-13, 1399/11/25

Registrant information

Name

mehrdad mokaram dori

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3858 3878

Email address

mokarradm@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-02-19, 1399/12/01

Expected recruitment end date

2021-12-22, 1400/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of preoperative ultrasound-guided femoral block on post-operative pain management in hip replacement surgery compare with postoperative intra venous morphine administration

Public title

Femoral nerve block for post operative pain control of hip replacement therapy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients 40 to 80 years old with hip fracture Candidate for hip replacement surgery ASA class 1 or 2 Written consent has received

Exclusion criteria:

History of consuming of opioids or antipsychotic drugs
Any kind of neurologic disease
History of hypersensitivity to anesthesia or local anesthetic drugs

Age

From **40 years** old to **80 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Envelop method in which one of the research group print and prepare envelopes by evolving randomized numbers from the Randomized.com site. The envelopes are sealed and invisible. After explaining of the study propose and receive the written consent the patient choose one envelop and enter to one the two groups of trial or control groups.

Blinding (investigator's opinion)

Single blinded

Blinding description

The analyzer will not aware of the intervention group and the data will be delivered to analyzer in just two groups of A and B.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Mashhad University of Medical Science

Street address

Pardis University, Mashhad University of Medical Science, Azadi Square

City

Mashhad

Province

Razavi Khorasan

Postal code

9177948564

Approval date

2021-01-23, 1399/11/04

Ethics committee reference number

IR.MUMS.MEDICAL.REC.1399.610

Health conditions studied**1****Description of health condition studied**

Post operative pain

ICD-10 code

Y83.4

ICD-10 code description

Other reconstructive surgery as the cause of abnormal reaction of the patient, or of later complication, without mention of misadventure at the time of the procedure

Primary outcomes**1****Description**

Pain score in questioner

Timepoint

1 hour after entering to the recovery and then every 4 hours for next 12 hours and the day after operation

Method of measurement

Pain score with numerical rating scale (NRS)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Under ultrasound guidance needling will be done with a nerve stimulator needle and after observation of quadriceps muscle contracture by 0.5 ampere, Femoral nerve will be blocked by injection of a solution contains 5 ml 2 percent Lidocaine and 5 ml 0.5 percent bupivacaine with 50 microgram fentanyl.

Category

Treatment - Drugs

2**Description**

Control group: In control group and in the case of the pain exacerbation more than 3 in NRS scale ; 0.05 mg per Kg Intravenous Morphine will be prescribed every 6 hours.

Category

Treatment - Drugs

Recruitment centers1**Recruitment center****Name of recruitment center**

Emam-Reza hospital

Full name of responsible person

Mehrddad Mokaram Dori

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Anesthesia Department, Imam Reza Hospital, Razi Ave.

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Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Mashhad University of Medical Sciences

Full name of responsible person

Mohsen Tafaghodi

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Pharmaceutics department, Pardis university, Pharmacology faculty, Vakilabad Blvd.

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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

Mashhad 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**

Mashhad University of Medical Sciences

Full name of responsible person

Mehrddad Mokaram Dori

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

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

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Full name of responsible person

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Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Only main outcome information could be shared

When the data will become available and for how long

After 6 month of the end of the study

To whom data/document is available

Other university researchers

Under which criteria data/document could be used

Authorized by mention of the reference

From where data/document is obtainable

Dr moulod Zolfaghari : moulod61@yahoo.com

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

Email the request and the answer will be sent in one month

Comments