

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

13 Jun 2026

### The Effect of Adding Magnesium Sulfate to Ropivacaine in Femoral Nerve Block before Spinal Anesthesia on Pain Management in Femoral Fracture Surgeries: A Randomized Clinical Trial

#### Protocol summary

##### Study aim

Effect of adding magnesium sulfate to ropivacaine on femoral nerve block before spinal anesthesia on pain management in femoral fracture surgeries

##### Design

Two arms parallel-group randomized clinical trial with a triple-blinded of 104 patients. Random allocation of samples is done by block method using Proc PLAN SAS.

##### Settings and conduct

This three-blind clinical trial study will be performed on 104 patients undergoing femoral fracture surgery (in two intervention and control groups) at Ayatollah Mousavi Hospital in Zanjan. Random allocation of samples is done by block method using Proc PLAN SAS. Visual analog scale and demographic information questionnaire will be used to measure postoperative pain. Questionnaires are completed by the researcher during the operation and at hours (immediately after the operation, 6, 12, and 24 hours after the operation).

##### Participants/Inclusion and exclusion criteria

-Inclusion criteria: American Society of Anesthesiologists (ASA) Class I & II; Patients candidates for femoral fracture surgery -Non-inclusion criteria: coagulation disorder; History of drug allergy; History of peripheral neuropathy; Existence of simultaneous fracture; History of mental disorder (based on medical record); Drug addiction

##### Intervention groups

Intervention group: Ultrasound-guided femoral nerve block (eZono AG/D-07743 Jena, Germany) will be performed before spinal anesthesia as 15 ml of ropivacaine 0.2% (made by MOLTEN)+0.5 ml of magnesium sulfate 50% (made by Shahid Ghazi Tabriz). Control group: Ultrasound-guided femoral nerve block (eZono AG/D-07743 Jena, Germany) will be performed before spinal anesthesia as 15 ml of ropivacaine 0.2% (made by MOLTEN)+0.5 ml of normal saline (made by

Shahid Ghazi Tabriz).

##### Main outcome variables

Postoperative pain

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20180325039148N5**

Registration date: **2021-10-19, 1400/07/27**

Registration timing: **prospective**

Last update: **2021-10-19, 1400/07/27**

Update count: **0**

##### Registration date

2021-10-19, 1400/07/27

##### Registrant information

##### Name

Saeed Jalili

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 24 3313 0001

##### Email address

jalilis45@zums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-10-23, 1400/08/01

##### Expected recruitment end date

2022-04-20, 1401/01/31

##### Actual recruitment start date

empty

**Actual recruitment end date**

empty

**Trial completion date**

empty

**Scientific title**

The Effect of Adding Magnesium Sulfate to Ropivacaine in Femoral Nerve Block before Spinal Anesthesia on Pain Management in Femoral Fracture Surgeries: A Randomized Clinical Trial

**Public title**

The effect of magnesium sulfate on lower limb anesthesia

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

18-75 years old American Society of Anesthesiologists (ASA) Class I & II Patients candidates for femoral fracture surgery

**Exclusion criteria:**

Coagulation disorder History of drug allergy History of peripheral neuropathy Existence of simultaneous fractures History of mental disorder (based on medical record) Drug addiction

**Age**

From **18 years** old to **75 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider
- Outcome assessor

**Sample size**

Target sample size: **104**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Samples will be assigned to the two groups by blocking the classification method based on age and sex. The blocks will be selected randomly with size 4. Proc PLAN SAS will be used to prepare the blocks and is given to the researcher who is responsible for collecting samples, and based on the code assigned to each patient (A, B, C, D), individuals are divided into two groups without a researcher's interference.

**Blinding (investigator's opinion)**

Triple blinded

**Blinding description**

Patients know that they are participating in a study aimed at investigating the effect of femoral nerve block with Ropivacaine + normal saline and femoral nerve block with Ropivacaine + magnesium sulfate on pain management in femoral fracture surgery, but are unaware that Ropivacaine + Normal saline or Ropivacaine + Magnesium sulfate is used in the block of the femoral nerve for them. Medications are coded, and the anesthetist who injects the medication does not

know what type of medication the patients are receiving. The person measuring the response or pain intensity will be unaware of the nature of the groups.

**Placebo**

Used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

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

Ethics committee of Zanjan University of Medical Sciences

**Street address**

Vice-Chancellor for Research and Technology, 3th Floor, 2th Bldg., Zanjan University of Medical Sciences, Azadi Blvd. Zanjan, IRAN.

**City**

Zanjan

**Province**

Zanjan

**Postal code**

4515613191

**Approval date**

2021-10-13, 1400/07/21

**Ethics committee reference number**

IR.ZUMS.REC.1400.297

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

femoral fracture

**ICD-10 code**

M80.05

**ICD-10 code description**

Age-related osteoporosis with current pathological fracture, femur

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

Determination of postoperative analgesia in Femoral fracture surgeries

**Timepoint**

Immediately after surgery, 6, 12 and 24 hours after surgery

**Method of measurement**

Visual analog scale of pain

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: Ultrasound-guided femoral nerve block (eZono AG/D-07743 Jena, Germany) will be performed before spinal anesthesia as 15 ml of ropivacaine 0.2% (made by MOLTEN) + 0.5 ml of magnesium sulfate 50% (made by Shahid Ghazi Tabriz).

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Ultrasound-guided femoral nerve block (eZono AG/D-07743 Jena, Germany) will be performed before spinal anesthesia as 15 ml of ropivacaine 0.2% (made by MOLTEN) + 0.5 ml of normal saline (made by Shahid Ghazi Tabriz).

#### Category

Treatment - Other

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Ayatollah Mousavi Hospital, Zanzan

##### Full name of responsible person

Saeed Jalili

##### Street address

Ayatollah Mousavi Hospital, Gavazang Blvd, Zanzan

##### City

Zanzan

##### Province

Zanzan

##### Postal code

4513956183

##### Phone

+98 24 3313 0000

##### Email

jalilis45@zums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Zanzan University of Medical Sciences

##### Full name of responsible person

Shoghli Alireza

##### Street address

Vice-Chancellor for Research and Technology, 3th Floor, 2th Bldg., Zanzan University of Medical

Sciences, Azadi Blvd. Zanzan, IRAN.

##### City

Zanzan

##### Province

Zanzan

##### Postal code

4515613191

##### Phone

+98 24 3315 6141

##### Email

shoghli@zums.ac.ir

#### Grant name

#### Grant code / Reference number

#### Is the source of funding the same sponsor organization/entity?

Yes

#### Title of funding source

Zanzan 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

Zanzan University of Medical Sciences

##### Full name of responsible person

Saeed Jalili

##### Position

Assistant Professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Anesthesiology

##### Street address

Ayatollah Mousavi Hospital, Gavazang Blvd, Zanzan

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##### Email

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## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Zanzan University of Medical Sciences

**Full name of responsible person**

Saeed Jalili

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Anesthesiology

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

**Justification/reason for indecision/not sharing IPD**

-

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

No - There is not a plan to make this available

**Clinical Study Report**

No - There is not a plan to make this available

**Analytic Code**

No - There is not a plan to make this available

**Data Dictionary**

No - There is not a plan to make this available

**Person responsible for updating data****Contact****Name of organization / entity**

Zanzan University of Medical Sciences

**Full name of responsible person**

Saeed Jalili

**Position**

Assistant Professor

**Latest degree**

Specialist