

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Assessment the effect of oxazepam administration on the amount of opioids consumption in patients after lower limb orthopedic surgeries

#### Protocol summary

##### Study aim

Investigating the effect of oxazepam on drug abuse reduction

##### Design

Randomization method In this study, the use of random blocks with quadruple blocks after random sequencing of this list was carried out using encapsulated packets. Finally, 90 envelopes containing the random sequences of each patient were provided to the original researcher. Took The process of random allocation and hiding the list was carried out by one of the authors who did not participate in the process of selecting, treating, collecting information

##### Settings and conduct

The location of the study of Shahid Rajaei Hospital of Qazvin Orthopedic section will be Patients with leg fractures requiring plate after signing the consent form are not aware of being in the control or intervention group

##### Participants/Inclusion and exclusion criteria

. Inclusion criteria include ages 20 to 60 years; candidates for orthopedic surgeries of the lower extremities; exclusion criteria including chronic renal failure; heart disease; alteration in consciousness; mental illness; diabetes; history of surgery; peripheral neuropathy; anemia; history of allergy to the drugs used in the study; history of using hypnotics; patients with poor collaboration; history of NSAIDS and drug abuse

##### Intervention groups

In the control group, after admission, the patient receives the drug as needed, but in the intervention group, in addition to receiving the opioid receptacle, he receives the oxazepam tablet as needed

##### Main outcome variables

Reducing drug use in the intervention group

#### General information

##### Reason for update

##### Acronym

-

##### IRCT registration information

IRCT registration number: **IRCT20161031030609N2**

Registration date: **2017-12-06, 1396/09/15**

Registration timing: **registered\_while\_recruiting**

Last update: **2017-12-06, 1396/09/15**

Update count: **0**

##### Registration date

2017-12-06, 1396/09/15

##### Registrant information

###### Name

Marzieh Asghari

###### Name of organization / entity

Rajaei Cardiovascular Research Center

###### Country

Iran (Islamic Republic of)

###### Phone

+98 28 3222 4667

###### Email address

asghary\_marzieh@rhc.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Qazvin University of Medical Sciences

##### Expected recruitment start date

2017-11-06, 1396/08/15

##### Expected recruitment end date

2018-02-04, 1396/11/15

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Assessment the effect of oxazepam administration on the amount of opioids consumption in patients after lower limb orthopedic surgeries

**Public title**

Assessment the effect of oxazepam administration on the pain of past orthopedic surgeries

**Purpose**

Treatment

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

Age 20 to 60 years old candidate for orthopedic surgeries of the lower extremities tend to Participate study

**Exclusion criteria:**

history of chronic renal failure heart disease abnormal consciousness having mental illness diabetes history of surgery peripheral neuropathy anemia History of allergy to the drugs used in the study the history of using hypnotic drugs poorly performing patients history of NSAIDS abuse opioide

**Age**

From **20 years** old to **60 years** old

**Gender**

Both

**Phase**

2

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **90**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization method In this study, the use of random blocks with quadruple blocks after random sequencing of this list was carried out using encapsulated packets. Finally, 90 envelopes containing the random sequences of each patient were provided to the original researcher. Took The process of random allocation and hiding the list was carried out by one of the authors who did not participate in the process of selecting, treating, collecting information

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

The participant will not be informed of the group after signing the consent form

**Placebo**

Not used

**Assignment**

Parallel

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

empty

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

Ethics committee of Qazvin University of Medical Sciences

**Street address**

Shahid Bahonar Blvd. Qazvin University of Medical Sciences

**City**

Qazvin

**Province**

Qazvin

**Postal code**

34197-59811

**Approval date**

2017-09-28, 1396/07/06

**Ethics committee reference number**

IR.QUMS.REC.1396.289

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

Orthopedic

**ICD-10 code**

M95-M99

**ICD-10 code description**

بیماری های عضلانی اسکلتی

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

reduce pain

**Timepoint**

0-30 second-6hours

**Method of measurement**

scale vas

**Secondary outcomes****1****Description**

reduce use of opioids

**Timepoint**

6 hours past surgeries

**Method of measurement**

record to nursing report

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

use of tablet ozaepam

**Category**

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

hospital shahid rajaee

**Full name of responsible person**

Marzieh Asghary

**Street address**

Shahid Bahonar Blvd. Qazvin University of Medical Sciences

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medicine@qums.ac.ir

**Web page address**

<http://sm.qums.ac.ir/Portal/Home>

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Qazvin University of Medical Sciences

**Full name of responsible person**

dr amir pemani

**Street address**

Qazvin- avenue shahd bahonar University of Medical Sciences

**City**

Shahid Bahonar Blvd, Qazvin, Iran

**Province**

Qazvin

**Postal code**

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**Email**

medicine@qums.ac.ir

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

Yes

**Title of funding source**

Qazvin 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**

hospital shahid rajaee

**Full name of responsible person**

marzieh asghary

**Position**

msc nursing

**Latest degree**

Master

**Other areas of specialty/work****Street address**

hospital shahid rajaee

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**Province**

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**Phone**

+98 28 3333 5800

**Fax****Email**

asghary\_marzieh@yahoo.com

**Web page address**

## Person responsible for scientific inquiries

**Contact****Name of organization / entity**

hospital shahid rajaee

**Full name of responsible person**

dr mahdi yusefi

**Position**

Orthopedic specialist

**Latest degree**

Specialist

**Other areas of specialty/work**

Orthopedics

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
university medical science qazvin

**Full name of responsible person**  
Marzieh Asghary

**Position**  
Nursing Student

**Latest degree**  
Master

**Other areas of specialty/work**  
Nursery

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hospital shahid rajaei

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**Province**  
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00

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**Email**  
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**Web page address**

### 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

Undecided - It is not yet known if there will be 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

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

#### Title and more details about the data/document

The total potential data is shared after the unidentifiable people are shared. The main outcomes of the study are shared

#### When the data will become available and for how long

6 months after completion

#### To whom data/document is available

Researchers working in academia and academia

#### Under which criteria data/document could be used

Use in later studies Use for medical decisions

#### From where data/document is obtainable

e-mail:\s hc nvdhtj asghary\_marzieh@yahoo.com

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

After receiving the email in the requester, it will be available in less than a week

#### Comments