# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

17 Sep 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 Rajaee 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 ozoxapam 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
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Iran (Islamic Republic of)
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**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 opiode
**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

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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

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Qazvin- avenue shahd bahonar University of Medical Sciences

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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**
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**

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## Person responsible for scientific inquiries

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**Position**
Orthopedic specialist

**Latest degree**
Specialist

**Other areas of specialty/work**
Orthopedics

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## Person responsible for updating data

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**Other areas of specialty/work**
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**Fax**

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asghary_marzieh@yahoo.com

**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**