

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

31 May 2026

### Comparison effect of Apotel and Pergabalin in reduce pain after in orthopedic surgery

#### Protocol summary

##### Study aim

Comparison effect of Apotel and Pergabalin in reduce pain after in orthopedic surgery

##### Design

This study is clinical trials and double blind.75 patients candidate orthopedic surgery in lower limb will enter in Valiasr hospital.patients will divide in three groups.We treat patients 150 miligram pregabalin 2 hours before surgery in intervention group.We treat patients 1 gram Apotel 20 minute before surgery in intervention group.We treat patients one capsule placebo before surgery in intervention group.We record pain in recovery, 2 and 12 and 24 hours after surgery. We record consumption of opioids in 24 hours in milligram.We record ramsy sedation score in 24 hours after surgery.

##### Settings and conduct

This study is clinical trials and double blind.75 patients candidate orthopedic surgery in lower limb will enter in Valiasr hospital in Arak city.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: candidate orthopedic surgery lower limb; 17 to 65 years; both of two gender Negative entry conditions: Coagulation disorders; Unwillingness to participate in the study; Severe hemodynamic instability; Hepatic, renal and cardiac disease; sensitivity to Pregabalin and Apotel

##### Intervention groups

We treat patients 150 miligram pregabalin 2 hours before surgery in intervention group.We treat patients 1 gram Apotel 20 minute before surgery in intervention group.We treat patients one capsule placebo before surgery in intervention group.

##### Main outcome variables

We record pain in recovery, 2 and 12 and 24 hours after surgery. We record consumption of opioids in 24 hours in milligram.We record ramsy sedation score in 24 hours after surgery.

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20141209020258N61**

Registration date: **2018-01-09, 1396/10/19**

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

Last update: **2018-01-09, 1396/10/19**

Update count: **0**

##### Registration date

2018-01-09, 1396/10/19

##### Registrant information

##### Name

Fariba Farokhi

##### Name of organization / entity

Arak University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 86 3222 2003

##### Email address

f.farokhi@arakmu.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2017-08-23, 1396/06/01

##### Expected recruitment end date

2019-12-22, 1398/10/01

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

**Scientific title**

Comparison effect of Apotel and Pergabalin in reduce pain after in orthopedic surgery

**Public title**

Comparison effect of Apotel and Pergabalin in reduce pain after in orthopedic surgery

**Purpose**

Treatment

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

candidate orthopedic surgery lower limb 17 to 65 years both of two gender

**Exclusion criteria:**

Coagulation disorders Unwillingness to participate in the study Severe hemodynamic instability Hepatic, renal and cardiac disease Sensitivity to Pregabalin and Apotel

**Age**

From **17 years** old to **65 years** old

**Gender**

Both

**Phase**

2-3

**Groups that have been masked**

- Participant
- Outcome assessor

**Sample size**

Target sample size: **75**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Random numbers table

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

The study is double-blind. The participant and the outcome evaluator are unaware. blindness in control group, we give normal saline in serum and capsule of placebo. blindness in intervention group, we give apotel in serum and capsule of placebo. blindness in another intervention group normal saline in serum and tab of Pregabalin. In this way, patients are not informed of the group they are in

**Placebo**

Used

**Assignment**

Parallel

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

empty

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

Ethics committee Arak University Of Medical Sciences

**Street address**

Vice chancellor for research, Payambar azam complex, Basij square, Sardasht, Arak

**City**

Arak

**Province**

Markazi

**Postal code**

38149578558

**Approval date**

2017-08-14, 1396/05/23

**Ethics committee reference number**

IR.ARAKMU.REC.1396.96

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

pain after surgery

**ICD-10 code**

G89

**ICD-10 code description**

Pain, not elsewhere classified

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

pain

**Timepoint**

We record pain in recovery, 2 and 12 and 24 hours after surgery.

**Method of measurement**

Visual Analog Sacle

**2****Description**

consumption of opioids

**Timepoint**

We record consumption of opioids in 24 hours in milligram.

**Method of measurement**

milligram

**3****Description**

sedation

**Timepoint**

We record ramsy sedation score in 24 hours after surgery.

**Method of measurement**

ramsy sedation score

**Secondary outcomes**

empty

## Intervention groups

### 1

#### Description

Intervention group: We treat patients 150 miligram pregabalin 2 hours before surgery in intervention group.

#### Category

Treatment - Drugs

### 2

#### Description

Intervention group: We treat patients 1 gram Apotel in 200 milliliter 20 minute before surgery in intervention group.

#### Category

Treatment - Drugs

### 3

#### Description

Control group: We treat patients one capsule placebo before surgery in intervention group.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Valiasr hospital

##### Full name of responsible person

Dr Mehran Azami

##### Street address

Valiasr Hospital, Valiasr square, Shahid Shirodi street

##### City

Arak

##### Province

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##### Postal code

3814957558

##### Phone

+98 86 3222 2003

##### Fax

+98 86 3222 2003

##### Email

m.azami@arakmu.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Arak University of Medical Sciences

##### Full name of responsible person

Dr Anoshirvani

##### Street address

Vice chancellor for research, Payambar Azam

Complex, Basij square, Sardasht, Arak

##### City

Arak

##### Province

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##### Postal code

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##### Phone

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##### Fax

+98 86 3222 2003

##### Email

anoshirvani@arakmu.ac.ir

#### Grant name

#### Grant code / Reference number

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

Yes

#### Title of funding source

Arak 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

Arak University of Medical Sciences

##### Full name of responsible person

Dr Alireza Kamali

##### Position

Assistant professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Anesthesiology

##### Street address

Valiasr Hospital, Valiasr square, Shahid Shirodi street

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##### Email

alikalaliir@yahoo.com

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Dr Mehran Azami

**Position**

Assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Orthopedics

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mazami@arakmu.ac.ir

## Person responsible for updating data

### Contact

**Name of organization / entity**

Arak University of Medical Sciences

**Full name of responsible person**

Dr Ali Nami damirchi

**Position**

resident of orthopedi

**Latest degree**

Specialist

**Other areas of specialty/work**

Orthopedics

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**Email**

ali.nami.damirchi@gmail.com

## 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**

Not applicable

**Data Dictionary**

Not applicable

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

When we publish article in journal.

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

After the article is published

**To whom data/document is available**

researcher in university

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

If there are additional questions

**From where data/document is obtainable**

Dr Mehran Azami

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

They have to write letters to the professors and the university

**Comments**