

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

Markazi

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

Markazi

Postal code

3814957558

Phone

+98 86 3222 2003

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

City

Arak

Province

Markazi

Postal code

3814957558

Phone

+98 86 3222 2003

Fax

+98 86 3222 2003

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

Street address

Valiasr Hospital, Valiasr square, Shahid Shirodi street

City

Arak

Province

Markazi

Postal code

3814957558

Phone

+98 86 3222 2003

Fax

+98 86 3222 2003

Email

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

Street address

Payambar Azam Complex, Basij square, Sardasht,

Arak

City

Arak

Province

Markazi

Postal code

3814957558

Phone

+98 86 3222 2003

Fax

+98 86 3222 2003

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