

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

A clinical trial comparing preoperative prescription of two drugs Celexib and Pregabalin on postoperative pain in patients volunteer Orthopedic surgery.

Protocol summary

Summary

Objectives: This study aimed to investigate the effect of preoperative prescription of two drugs Celexib and Pregabalin on postoperative pain after Orthopedic surgery is performed on volunteer patients. **Study design:** Randomized, double-blind, placebo-controlled, single-center, two trials study. **Study setting and conduct:** Before entering the operating room, patients are randomly with table of random numbers divided into three groups Celexib, pregabalin and placebo, as we do without any premedication to patients such as: Morphine, fentanyl, benzodiazepine, and so on. After referring to the ward, three hours before surgery, one patient is placed randomly in Celexib group with dose of 200 mg, one patient is placed randomly in Pregabalin group with dose of 150 mg and one patient is placed randomly in the placebo group with dose of 10 ml of normal saline 0.9% intravenously through an Angiocatheter. The method of injection and maintenance of anesthesia for all patients is the same. Presence or absence of pain in all three groups is investigated by an experienced person who is not aware of the type of drug by filling out the questionnaire, according to the pain score that stated in the questionnaire, at the end of specific time in recovery room, i.e. 45 minutes after regaining consciousness as well as, three hours after entering the ward. **Participants** including major eligibility criteria: Volunteer Orthopedic surgery patients between 18 and 65 years. Major exclusive criteria: People under 18 and over 65 years; Drug addicts; Diabetics; Patients with Cardiovascular Disorders; Patients who are taking Steroids for any reason; Patients who are taking Nonsteroidal anti-inflammatory drugs ongoing; Pregnant women; Patients who are taking Antidepressant and Antipsychotic drugs; Patients with fractures of the femor and pelvis. **Sample:** Three groups of 40 patients each. **Interventions:** Prescription of Celexib in one group, Pregabalin in

another group and 0.9% Normal saline in the third group before surgery in order to evaluate postoperative pain in each group. **The intervening time:** Three hours before entering to Operation room. **Variables of main outcome:** Pain is as the independent continual variable and drug is as the independent nominal variable.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016012715281N5**

Registration date: **2016-08-06, 1395/05/16**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-08-06, 1395/05/16

Registrant information

Name

Seyedebrahim Sadeghi

Name of organization / entity

Shiraz University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor of research, Shiraz University of Medical Sciences (International Branch)

Expected recruitment start date

2016-06-21, 1395/04/01
Expected recruitment end date
 2016-10-22, 1395/08/01
Actual recruitment start date
 empty
Actual recruitment end date
 empty
Trial completion date
 empty

Scientific title
 A clinical trial comparing preoperative prescription of two drugs Celexib and Pregabalin on postoperative pain in patients volunteer Orthopedic surgery.

Public title
 Celexib and Pregabalin effect on pain after Orthopedic surgery.

Purpose
 Supportive

Inclusion/Exclusion criteria
 Inclusion criteria: Volunteer Orthopedic surgery patients between 18 and 65 years. Exclusion criteria: People under 18 and over 65 years; Drug addicts; Diabetics; Patients with Cardiovascular Disorders; Patients who are taking Steroids for any reason; Patients who are taking Nonsteroidal anti-inflammatory drugs ongoing; Pregnant women; Patients who are taking Antidepressant and Antipsychotic drugs; Patients with fractures of the femur and pelvis.

Age
 No age limit

Gender
 Both

Phase
 2-3

Groups that have been masked
No information

Sample size
 Target sample size: **120**

Randomization (investigator's opinion)
 Randomized

Randomization description

Blinding (investigator's opinion)
 Double blinded

Blinding description

Placebo
 Used

Assignment
 Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences (International Branch)

Street address

Shiraz University of Medical Sciences(International Branch), Injuries and Burn Hospital entrance, 3rd km of Sadra road.

City

Shiraz

Postal code

7144716699

Approval date

2016-06-07, 1395/03/18

Ethics committee reference number

IR.SUMS.REC.1395.36

Health conditions studied

1

Description of health condition studied

The pain after Orthopedic surgeries.

ICD-10 code

T84.9

ICD-10 code description

Other Complication of Orthopedic surgeries.

Primary outcomes

1

Description

Pain level after Orthopedic surgery.

Timepoint

The pain is investigated 45 minutes after the end of anesthesia in the recovery room and three hours after entering the ward.

Method of measurement

Visual and intrrogrative measure of pain from the patient and complete the questionnaire.

Secondary outcomes

empty

Intervention groups

1

Description

The control group: The first group; 10 mL of 0.9% Normal Saline IV through Angiocatheter; Three hours before entering the Operation room.

Category

Placebo

2

Description

The intervention group: The second group; Celexib of abooreihan factory with the dose of 200 mg orally; Three hours before entering the Operation room.

Category

3**Description**

The intervention group: The group third; Peregabalin of abooreihan factory with the dose of 150 mg orally; Three hours before entering the Operation room.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Marvdasht Martyr Motahari Hospital

Full name of responsible person

Dr. Seyed Ebrahim Sadeghi

Street address

Marvdasht Martyr Motahari Hospital, After Teacher underpass, Marvdasht.

City

Marvdasht

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Vice chancellor for research, Shiraz University of Medical Sciences (International Branch)

Full name of responsible person

Dr. Ali Akbari

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City

Shiraz

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

Yes

Title of funding source

Vice chancellor for research, Shiraz University of Medical Sciences (International Branch)

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin**Type of organization providing the funding**

empty

Person responsible for general inquiries**Contact****Name of organization / entity**

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Seyed Ebrahim Sadeghi

Position

Anesthesiologist with Anesthesia Fellowship of Cardiovascular surgery, Assistant professor of Anesth

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

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Email

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Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty