

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

A Clinical trial of Preoperative Single dose of oral Pergabalin in adult-impacted third molar surgery.

Protocol summary

Summary

(1) Objectives: Postoperative pain control after surgery is one of the main issues in the care of patients and has Important role in accelerating the patient's general condition that improve healing in general. (2) Design: This study was a double-blind clinical trial. 210 patients were admitted to dental school who were randomly divided into two groups of 105 patients. The study was approved by the Ethics Committee of Shiraz University of Medical Sciences and written informed consent for surgery of impacted tooth is done in patient with physical status of 1 class. (3) Setting and conduct: Groups of cases received pregabalin 75 mg orally one hour before third molar surgery and the control group received placebo . (4) Participants including major eligibility criteria: Inclusion criteria included : Older than 18 and younger than 51 years : ASA physical status I (without diseases) were selected : and Exclusion criteria included: underlying disease : Obesity (weight more than 20% above ideal weight : Short stature (less than 140 cm) : A history of anti-epileptic drugs or alcohol addiction : History of allergy to opioids : Renal dysfunction : Nervous system diseases : Cardiovascular diseases : History of chronic pain and antiepileptic drugs will be excluded . (5) Intervention: The first group (105 patients) will received single dose of pregabalin 75 mg orally and in the second group (control) consisted of 105 patients who received placebo with 100 ml of water and administered orally one hour before impacted wisdom teeth surgery. (6) main outcome measures : Hemodynamics parameters (heart rate, systolic and diastolic blood pressure) in four steps (one hour before surgery, immediately before the operation, immediately after surgery and time of discharge) will be measured . Postoperative pain in patients with visual pain scale (VAS) will be measured four hours after surgery, And in the lack of any side effects and ensuring of the hemodynamic stability they are discharged.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201212241674N6**

Registration date: **2013-07-20, 1392/04/29**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-07-20, 1392/04/29

Registrant information

Name

Hamid Reza Eftekharian

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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Email address

eftekhahr@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shiraz University of Medical Sciences

Expected recruitment start date

2012-05-21, 1391/03/01

Expected recruitment end date

2013-05-22, 1392/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Clinical trial of Preoperative Single dose of oral Pergabalin in adult- impacted third molar surgery.

Public title

Evaluation of Pregabalin oral sedation in impacted third molar surgery .

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria included : Older than 18 and younger than 51 years old : ASA physical status I (without diseases) were selected : and Exclusion criteria included: underlying disease : Obesity (weight more than 20% above ideal weight : Short stature (less than 140 cm) : A history of anti-epileptic drugs or alcohol addiction : History of allergy to opioids : Renal dysfunction : Nervous system diseases : Cardiovascular diseases : History of chronic pain and anticonvulsant drugs .

Age

From **18 years** old to **51 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **210**

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

Street address

Vice chancellor for research , headquarters of Shiraz University of Medical Sciences , Shiraz University of Medical Sciences, Zand Street, Shiraz

City

Shiraz

Postal code

713451978

Approval date

2011-06-20, 1390/03/30

Ethics committee reference number

CT80591022

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

Impacted third molar surgery

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Measurement of blood pressure and heart rate

Timepoint

One hour before surgery , end of surgery and during discharge

Method of measurement

Digital blood pressure measuring device

2**Description**

Measure the level of sedation

Timepoint

before surgery , end of surgery and during discharge

Method of measurement

Ramsay Sedation Scale

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

patient's satisfaction

Timepoint

end of surgery

Method of measurement

ranking from excellent, very good, good, average, poor

2**Description**

Dentist' satisfaction from cooperation of the patient

Timepoint

end of surgery

Method of measurement

ranking from excellent, very good, good, average, poor

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

Groups of cases received Pergabalin 75 miligram single dose orally one hour before third molar surgery

Category

Treatment - Drugs

2**Description**

Control groups received Placebo orally one hour before third molar surgery

Category

Treatment - Drugs

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

Shiraz Dentistry Medical School

Full name of responsible person

Hamid Reza Arabiyon

Street address

Department of Maxillofacial Surgery , Shiraz Dentistry Medical School , Ghasredasht Street , Shiraz

City

Shiraz

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

Vice-Chancellery of Research and Technology, Shiraz University Of Medical Sciences

Full name of responsible person

Gholam Reza Hatam

Street address

Vice chancellor for research, Seventh Floor , Next to Red Crescent Organization , headquarters of Shiraz University of Medical Sciences , Shiraz University of Medical Sciences, Zand Street , Shiraz

City

Shiraz

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

Yes

Title of funding source

Vice-Chancellery of Research and Technology, Shiraz University Of Medical Sciences

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

Hamid Reza Eftekharian

Position

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

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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