Clinical Trial Protocol
Iranian Registry of Clinical Trials

23 Jun 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)
Phone
+98 71 3636 4001
Email address
eftekharhr@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
Assistant Professor, Department of Maxillofacial Surgery
Other areas of specialty/work
Street address
Chamran Hospital, Chamran Blvd., Shiraz
City
Shiraz
Postal code
7183856793
Phone
+98 71 1648 3783
Fax
+98 71 1623 4507
Email
eftekharhr@sums.ac.ir
Web page address
www.sums.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Shiraz University Of Medical Sciences
Full name of responsible person
Hamid Reza Eftekharian
Position
Assistant Professor, Department of Maxillofacial Surgery
Other areas of specialty/work
Street address
Chamran Hospital, Chamran Blvd., Shiraz
City
Shiraz
Postal code
7183856793
Phone
+98 71 1648 3783
Fax
Email
eftekharhr@sums.ac.ir
Web page address
www.sums.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Shiraz University Of Medical Sciences
Full name of responsible person
Hamid Reza Eftekharian
Position
Assistant Professor, Department of Maxillofacial Surgery

Other areas of specialty/work

Street address

Chamran Hospital, Chamran Blvd., Shiraz

City

Shiraz

Postal code

7183856793

Phone

+98 71 1648 3783

Fax

Email

eftekharhr@sums.ac.ir

Web page address

www.sums.ac.ir

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