Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparative clinical trial of low dose Pregabalin versus Gelofen in decreasing postoperative pain in patients after mandibular third molar surgery

Protocol summary

Summary

The purpose of this study is Comparison of low dose Pregabalin versus Gelofen on postoperative pain reduction in third molar extraction patients. In this randomized, single blind clinical trial, a number of twenty five patients, 18 – 40 yr old, inclusion criteria: candidate for third molar extraction; lack of severe cardiac and mental disease; consent to take a share in the study and exclusion criteria: history of drug allergy; opiate and sedative use. According to the random numbers chart they are split into two groups: Pregabalin and Gelofen. At the end of surgery study group takes 75 milligram Pregabalin orally or 400 milligram Gelofen orally with a glass of water. Third molar extraction is performed by one surgeon with same surgical technique under local anesthesia. One month afterwards, the procedure will repeat for contralateral tooth and the drug will change. At the end of surgery before discharge, and every two hours until twelve hours after surgery, pain measure and record by a collaborator who does not know about grouping by using a visual index (Visual Analogue Scale) and analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016122131501N1**
Registration date: **2017-05-26, 1396/03/05**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-05-26, 1396/03/05

Registrant information

Name
Parsia Choubsaz
Name of organization / entity
Shahid Beheshti School of Dentistry
Country
Iran (Islamic Republic of)
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parsia.choubsaz@sbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Sahid Beheshti School of Dentistry

Expected recruitment start date

2017-02-19, 1395/12/01

Expected recruitment end date

2018-03-21, 1397/01/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative clinical trial of low dose Pregabalin versus Gelofen in decreasing postoperative pain in patients after mandibular third molar surgery

Public title

Effect of low dose Pregabalin versus Gelofen for postoperative pain

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: candidate for third molar extraction;

lack of severe cardiac and mental disease; consent to take part in the study Exclusion criteria: history of drug allergy; opiate use; sedative use

Age

From **18 years** old to **40 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **25**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Crossover

Other design features

Randomization was performed by using random numbers chart

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Shahid Beheshti University of Medical Sciences,

Street address

School of Dentistry, Daneshjoo Blvd, Evin, Shahid Chamran Highway

City

Tehran

Postal code

1983963113

Approval date

2017-02-18, 1395/11/30

Ethics committee reference number

IR.SBMU.RIDS.REC.1395.392

Health conditions studied

1

Description of health condition studied

Pain after third molar surgery

ICD-10 code

K010

ICD-10 code description

Embedded teeth

Primary outcomes

1

Description

Pain

Timepoint

Before intervention, and every 2 hours in12 hours after intervention

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group:Pregabalin 75 mg oral capsules (lyrics -Pfizer company) with a glass of water at the end of surgery

Category

Prevention

2

Description

Control group:Gelofen 200 milligram oral capsules(Ibuprofen -Doona pharma company) with a glass of water at the end of surgery

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Sahid Beheshti School of Dentistry

Full name of responsible person

Dr. Azita Tehranchi

Street address

School of Dentistry, Daneshjoo Blvd, Evin, Shahid Chamran Highway

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Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr. Azita Tehranchi

Street address

School of Dentistry, Daneshjoo Blvd, Evin, Shahid Chamran Highway

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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, Shahid Beheshti 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

Shahid Beheshti University of Medical Sciensec

Full name of responsible person

Parsia Choubsaz

Position

Dentistry student

Other areas of specialty/work

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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