

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Postoperative pain management after impacted third molar surgery with perioperative oral Lamotrigine.

Protocol summary

Summary

(1) Objectives: Lamotrigine, a new antiepileptic drug, has analgesic properties in its antisodium and antiglutamatergic effects. It may prevent postoperative pain. The purpose of this study was to evaluate the ability of oral Lamotrigine for postoperative pain reduction in impacted third molar surgery. (2) Design: This is a double-blind randomised clinical trial study, that evaluate the effect of oral Lamotrigine on postoperative pain reduction in patients requiring impacted third molar surgery whom will be referred to school of dentistry of shiraz medical sciences. The following parameters such as: Individual patient information, medical history, the patient's hemodynamic values before- during and after surgery, duration of operation will be recorded. Severity of pain was evaluated by visual analogue scale (VAS) (100-mm) and the amount of analgesic consumption after surgery, was recorded in maxillofacial ward. pain was measured after patient transferred to recovery room. After surgery, the pain was assessed on a visual analogue scale (VAS) at intervals of 1/2 hr at rest. Total analgesic consumption in the first 12hr after surgery was also recorded. (3) Setting and conduct: A total of 50 adult patients were selected for this randomized controlled trial. All subjects were divided into two groups to receive Lamotrigine or placebo. While anesthesiologist, and student project manager would be unaware of an intravenous drugs. (Medications taken by nurses are randomly coded). An informed consent approved by the Ethics Committee of the Shiraz University of Medical Sciences. The anesthesiologist administered 200 mg of lamotrigine orally with 20 cc water in study group and in the control group patients received placebo. Blood pressure and heart rate will be monitored, postoperative pain and necessity for postoperative analgesic immediately after surgery, in the recovery room and until 4 hours after operation will be calculated and recorded. (4) Participants including major eligibility criteria: Inclusion criteria included 15-25 year

old patients whom were scheduled to undergo impacted third molar surgery! Subjects who had systemic disease and history of drug consumption, history of drug allergic reaction, hepatic and renal dysfunction and lack of signed informed consent will be excluded from the study sample . (5) Intervention: Patients in the study group will be received an 200 mg Lamotrigine orally 1 hr. before surgery and the placebo group will receive placebo as same route of administration. (6) main outcome measures: Primary outcome measure was evaluating pain intensity over 16 hours after surgery. Secondary efficacy measures included analgesic consumption and safety and tolerability of lamotrigine. During surgery heart rate, blood pressure and blood oxygen saturation is recorded at specified intervals and at the end of the operation analgesics usage were recorded. After surgery the patients were monitored for up to 4 hours in the recovery room and pain intensity (VAS 100-mm) is measured by a person who was uninformed about case and control groups every half hour. Pain relief drug consumption for patients will be recorded up to 12 hours in home by telephone. post-operative complications will be asked in the questionnaire. Patient's satisfaction was evaluated as poor (0), moderate (1), good (2), and excellent (3).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201510111674N12**

Registration date: **2015-10-21, 1394/07/29**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-10-21, 1394/07/29

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

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

Expected recruitment start date

2015-10-23, 1394/08/01

Expected recruitment end date

2016-06-20, 1395/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Postoperative pain management after impacted third molar surgery with perioperative oral Lamotrigine.

Public title

Effectiveness of acute postoperative pain management of oral Lamotrigine after impacted third molar surgery.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria included: The patients with systemic disease and no history of drug use, and willingness to cooperate in this study are enrolled: Exclusion criteria included known allergy to the study drug, hepatic and renal dysfunction and lack of signed informed consent will be excluded.

Age

From **15 years** old to **25 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Used

Assignment

Parallel

Other design features

It has been explained.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics Committee of Shiraz University of Medical Sciences

Street address

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

City

Shiraz

Postal code

71345-1978

Approval date

2015-06-28, 1394/04/07

Ethics committee reference number

CT-P-94-56908

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

Impacted teeth

ICD-10 code

K01.1

ICD-10 code description

An impacted tooth is a tooth that has failed to erupt because of obstruction by another tooth.

Primary outcomes**1****Description**

Intensity of postoperative pain

Timepoint

Immediately after surgery to 12 hours after surgery

Method of measurement

VAS

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

Patient's level of satisfaction

Timepoint

Immediately after surgery to 12 hours after surgery

Method of measurement

poor (0), moderate (1), good (2), and excellent (3)

2

Description

post-operative complications of Lamotrigine

Timepoint

Immediately after surgery to 12 hours after surgery

Method of measurement

Nursing reports

Intervention groups

1

Description

Drug is administered with dose of 200 tablets of Lamotrigine orally with about 20 cc of water are given to the patient's study 1 hours before surgery.

Category

Treatment - Drugs

2

Description

The second group or control group received placebo with about 20 cc of water 1 hours before surgery.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center**Name of recruitment center**

Shiraz School of Dentistry

Full name of responsible person

Hamed Modanlou Juibari

Street address

Department of Craniomaxillofacial Surgery, Shiraz University of Medical Sciences, Shiraz, Iran

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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

Sayed Basir Hashemi

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

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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-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 School of Dentistry

Full name of responsible person

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Position

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Shiraz

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*