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 Lamotrigin 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 reffered 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 analoug scale (VAS) (100-mm) and the amount of analgesic consumption after surgery, was recorded in maxillofacial ward. pain was measured after patient transfered 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 Lamortigine 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 molarl 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. befor 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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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
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Department of Craniomaxillofacial Surgery, Shiraz University of Medical Sciences, Shiraz, Iran
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
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

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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