

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Aug 2026

Clinical trial to comparison of bupivacaine(local) and mefenamic acid on mean pain score reported during the first 24 hours after surgical extraction of third molar, in patients with similar bilateral impacted lower third molar.

Protocol summary

Summary

Objectives: Determination of the effect of injection of bupivacaine by patient into the tooth socket on pain management after surgical extraction of impacted lower third molar. Design: randomized, double blind, cross-over, placebo control, with in groups, single center, phase 2-3 trial. Participants including major eligibility criteria: major inclusion criteria: Patients with similar bilateral impacted lower third molar. major exclusion criteria: The length of two surgery of one patient have more than 10 min difference. Target sample size: 48. Setting and conduct: After each surgery of one patient that is performed with a time span of at least a week, he randomly takes bupivacaine+ placebo of mefenamic acid or mefenamic acid+ normal saline (placebo of bupivacaine). Intervention: After each surgery a catheter fix to second molar that patient can inject bupivacaine or normal saline every 2 hours in to the socket of impacted tooth through that. and also they should eat mefenamic acid or placebo of mefenamic acid every 8 hours. Time of intervention: During 24 hours following surgery(eating mefenamic or placebo of mefenamic) and 12 hours after surgery(injection of bupivacaine or normal saline). Main outcome measures: mean pain score reported by patients during the first 24 hours after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201204199515N1**
Registration date: **2013-01-15, 1391/10/26**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-01-15, 1391/10/26

Registrant information

Name

Ideh Talimkhani

Name of organization / entity

Hamadan faculty of dentistry

Country

Iran (Islamic Republic of)

Phone

+98 81 1824 2144

Email address

i.talimkhani@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Investigator

Expected recruitment start date

2012-04-19, 1391/01/31

Expected recruitment end date

2012-11-20, 1391/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial to comparison of bupivacaine(local) and mefenamic acid on mean pain score reported during the first 24 hours after surgical extraction of third molar, in patients with similar bilateral impacted lower third molar.

Public title

Evaluation of the effect of injection of bupivacaine by patient into the tooth socket on pain management after surgical extraction of impacted lower third molar

Purpose
Other

Inclusion/Exclusion criteria
Major inclusion criteria: The patients with similar bilateral impacted lower third molar; Patients that have no contraindications for oral surgery; Patients that are able to understand the method of our study. Major exclusion criteria: The length of two surgery of one patient have more than 10 min difference; Not using of drug according to the method that is trained.

Age
No age limit

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **48**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hamadan University of Medical Sciences

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh St, Hamadan, Iran

City

Hamadan

Postal code

65178

Approval date

2012-01-05, 1390/10/15

Ethics committee reference number

3592/9/35/16/د/پ

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

Post surgical pain

Timepoint

24 hours following surgery

Method of measurement

Visual Analogue Scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Placebo of mefenamic acid 250 mg, every 8 hours during 24 hours following surgery.

Category

Placebo

2

Description

Intervention group: Injection of 0.3 cc bupivacaine 0.5% in to the tooth socket, every 2 hours during 12 hours following surgery.

Category

Treatment - Drugs

3

Description

Control group: Injection of 0.3cc normal saline in to the tooth socket, every 2 hours during 12 hours following surgery.

Category

Placebo

4

Description

Control group: Mefenamic acid 250 mg, every 8 hours during 24 hours following surgery.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hamadan faculty of dentistry

Full name of responsible person

Ideh Talimkhani

Street address

Faculty of dentistry, Hamadan University of Medical Sciences, Shahid Fahmideh St, Hamadan, Iran

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Hamedan University of Medical Sciences

Full name of responsible person

Heidar Tavalani

Street address

Vice chancellor for research, Hamedan University of Medical Sciences, Shahid Fahmideh St, Hamadan, Iran

City

Hamadan

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, Hamedan 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

Hamadan faculty of dentistry

Full name of responsible person

Ideh Talimkhani

Position

General dentist

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

No381, block C4, Saidiyeh St, Hamadan, Iran

City

Hamadan

Postal code

6516953975

Phone

+98 81 1824 2144

Fax

+98 81 1824 2144

Email

ideatalimkhani@yahoo.com, i.talimkhani@umsha.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Hamadan faculty of dentistry

Full name of responsible person

Mohammad Reza Jamalpour

Position

oral and maxillofacial surgeon

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

Department of oral and maxillofacial surgery, Faculty of dentistry, Hamadan University of Medical Sciences, Shahid Fahmideh St, Hamadan, Iran

City

Hamadan

Postal code

6517838677

Phone

+98 81 1838 1081

Fax

+98 81 1835 1200

Email

jamalpour@umsha.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Hamadan Faculty of dentistry

Full name of responsible person

Ideh Talimkhani

Position

General dentist

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

No381, block C4, Saidiyeh St, Hamadan, Iran.

City

Hamadan

Postal code

6516953975

Phone

+98 81 1824 2144

Fax

+98 81 1824 2144

Email

ideatalimkhani@yahoo.com, i.talimkhani@umsha.ac.ir

Web page address

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