

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of Gelophen administration on mandibular impacted third molar surgery on pain reduction after surgery between men and women

Protocol summary

Study aim

Comparison of the effect of prescribing Gelophen on mandibular maxillary third molar surgery on pain reduction after surgery between men and women

Design

This study was non-control group and all patients referred to the diagnosis of impacted third molar with surgical indications and entry conditions were selected.

Settings and conduct

In this clinical trial study, all patients referring to the dental clinic of Khorramabad University of Medical Sciences who have implicated in the evaluation of impacted third molar are included in the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Impacted mandibular third molar, third molar without caries, third molar without a pericoronitis, a lack of vision of the impacted molar with the eye, an impacted molar that requires surgery to remove the need for piece of bone and teeth. Exclusion criteria: Having a history of disease, history of digestive diseases, history of systemic diseases such as diabetes, kidney failure, liver failure, history of allergy to aspirin and its similar compounds, patients with a history of addiction, no-referral, non-response of the phone for any reason, incidence of severe complications and patient death, use of drugs with anti-pain and anti-inflammatory properties that interfere with NSAIDs.

Intervention groups

Two Gelofen 400 mg, 1 hours before impacted third molar surgery

Main outcome variables

pain intensity

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180702040302N1**

Registration date: **2018-08-01, 1397/05/10**

Registration timing: **retrospective**

Last update: **2018-08-01, 1397/05/10**

Update count: **0**

Registration date

2018-08-01, 1397/05/10

Registrant information

Name

Ehsan Shafiei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 3220 7826

Email address

shafli.e@lums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-04-11, 1396/01/22

Expected recruitment end date

2018-04-11, 1397/01/22

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of Gelophen administration on mandibular impacted third molar surgery on pain reduction after surgery between men and women

Public title

evaluation of decreasing pain of impacted wisdom teeth

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Impacted mandibular third molar Third molar without caries Third molar without a pericoronitis A lack of vision of the impacted molar with the eye An impacted molar that requires surgery to remove the need for piece of bone and teeth

Exclusion criteria:

Having a history of disease History of digestive diseases History of systemic diseases such as diabetes, kidney failure, liver failure History of allergy to aspirin and its similar compounds Patients with a history of addiction No-referral Non-response of the phone for any reason Incidence of severe complications and patient death, Use of drugs with anti-pain and anti-inflammatory properties that interfere with NSAIDs.

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Khorramabad University of Medical Sciences

Street address

Research & Technology Dept, Kamalvand Pardis, Lorestan University of Medical Sciences, Khorramabad, Lorestan

City

Khorramabad

Province

Lorestan

Postal code

6814989468

Approval date

2018-05-12, 1397/02/22

Ethics committee reference number

IR.LUMS.REC.1397.026

Health conditions studied

1

Description of health condition studied

Pain control

ICD-10 code

Chapter V

ICD-10 code description

F45.4 Persistent somatoform pain disorder

Primary outcomes

1

Description

Pain intensity

Timepoint

2,4,6,6,8, 12,24,72 hours after surgery

Method of measurement

Standard questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Two Gelofen 400 mg 1 hours after impacted wisdom teeth

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dental Clinic, Khorramabad University of Medical Sciences

Full name of responsible person

Dr. Ehsan Shafiei

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Lorestan University of Medical Sciences, Khorramabad, Lorestan

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Larestan University of Medical Sciences

Full name of responsible person

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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

Larestan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Larestan University of Medical Sciences

Full name of responsible person

Dr. Mosayeb Masoumi Nejad

Position

General practitioner

Latest degree

Medical doctor

Other areas of specialty/work

Medical Education

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Person responsible for scientific inquiries

Contact

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Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Oral and Maxillofacial Surgery

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Latest degree

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Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable