

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Compare the effect of prescription Gelofen before and after impacted mandibular third molar surgery on the onset and duration of pain after surgery.

Protocol summary

Summary

1) Objectives The aim of this study is to investigating the effect of Gelofen prescription in reduction of pain after impacted third molar surgery that with choose best time to prescribe is decreased the pain problem after surgery. 2) Design Research with design of clinical trial, randomized controlled and split mouth. All patients who have indication for impacted tooth extraction of mandible in two side and after justification of design, and declare their agreement to cooperation with this plan, and have not been any problem for surgery, will be examined. 3) Procedure Each side of patients' mandible were divided into experimental group (prescription before surgery) and control group (prescription after surgery). Gelofen 400mg will prescribed for each group. By questioning of patients, when begin their pain after surgery, and that have received the first painkiller tablet, become distinguished and recorded, and also by asking patients will determined and recorded the number of used painkiller in 12 hours. Time of pain appearing (when first tablet used) and also the number of used tablet in two group assessed by t-test. For experimental group prescribed Gelofen 400mg half an hour before surgery and for control group which will done in next section, prescribed a Gelofen 400mg immediately after surgery. This study will be done on 20 person (40 sample). 4) Participants Inclusion criteria Patients who have been indication for impacted tooth extraction of mandible in two side with same dormancy and express their consciously tendency to cooperation with this plan. Exclusion criteria Present of peri coronal acute and chronic inflammation; used tablet except considered tablet; pregnant person; having systematic problems; individuals who used steroid medicine, anti-depressant and antibiotics; individuals who have prohibition to this used medicine. 5) Interventions One side of patient's mandible appointed experimental group and the other

side was control group. For control group prescribed Gelofen half an hour before surgery and for experimental group prescribed Gelofen immediately after surgery. 6) Main outcome variables Main variables were the time of pain beginning and the number of used tablet in 12 hours after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017030732929N1**

Registration date: **2017-05-16, 1396/02/26**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-05-16, 1396/02/26

Registrant information

Name

Fina Navi

Name of organization / entity

Islamic Azad University Tehran Dental Branch

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Islamic Azad University Tehran Dental Branch

Expected recruitment start date

2016-12-24, 1395/10/04
Expected recruitment end date
2017-05-10, 1396/02/20
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Compare the effect of prescription Gelofen before and after impacted mandibular third molar surgery on the onset and duration of pain after surgery.

Public title
The effect of Gelofen prescription in reduction of pain after impacted wisdom teeth surgery

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria Patients who have been indication for impacted tooth extraction of mandible in two side with same dormancy and express their consciously tendency to cooperation with this plan. Exclusion criteria Present of peri coronal acute and chronic inflammation; used tablet except considered tablet; pregnant person; having systematic problems; individuals who used steroid medicine, anti-depressant and antibiotics; individuals who have prohibition to this used medicine.

Age
No age limit

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **40**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee

Ethics Committee of Islamic Azad University Tehran dental Branch
Street address
10th Neistan, Pasdaran street
City
Tehran
Postal code
Approval date
2016-11-26, 1395/09/06
Ethics committee reference number
IR.IAU.DENTAL.REC.1395,10

Health conditions studied

1

Description of health condition studied
Impacted tooth

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
Time of pain appearing
Timepoint
Till 12 hour after surgery
Method of measurement
Ask the patient and registered.

2

Description
Number of tablet used
Timepoint
Till 12 hour after surgery
Method of measurement
Ask the patient and registered.

Secondary outcomes

empty

Intervention groups

1

Description
Half an hour before surgery prescribed Gelofen tablets 400 mg for experimental group.
Category
Treatment - Drugs

2

Description
Immediately after surgery prescribed Gelofen tablets 400

mg for control group.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Islamic Azad University Tehran Dental Branch
Full name of responsible person
Eshagh Lasemi
Street address
10th Neistan, Pasdaran street
City
Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Islamic Azad University
Tehran Dental Branch
Full name of responsible person
Dr Arash Azizi
Street address
10th Neistan street, Pasdaran street
City
Tehran
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, Islamic Azad University
Tehran Dental Branch
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
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Full name of responsible person
Fina Navi

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Person responsible for updating data

Contact

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