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
+98 912 201 5179
Email address
f_navi@dentaliau.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Islamic Azad Univercity 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 Univercity 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 exprimental 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 Univercity 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 Univercity 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 Univercity 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

Islamic Azad Univercity Tehran Dental Branch

Full name of responsible person

Fina Navi

Position

Faculty member

Other areas of specialty/work

Street address

10th Neistan street, Pasdaran street

City

Tehran

Postal code

Phone

+98 21227663460

Fax

Email

f_navi@dentaliau.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad Univercity Tehran Dental Branch

Full name of responsible person

Fina Navi

Position

Maxillofacial surgeon

Other areas of specialty/work

Street address

10th Neistan street, Pasdaran street

City

Tehran

Postal code

Phone

+98 21 2276 3460

Fax

Email

f_navi@dentaliau.ac.ir

Web page address

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