

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

Comparison of Naproxen and Gelofen for Pain Relief in the Third Molar Surgery: A single-blind randomized clinical trial study

Protocol summary

Study aim

Compare analgesic effect of Gelofen and Naproxen in lower third molar surgery

Design

Block randomization, randomized patients into four groups (n=20); Pre-Gelofen group: Patients received 400 mg Gelofen 30 minute before surgery and continued taking it every 6 hours postoperatively, Gelofen group: patients received 400 mg Gelofen immediately after the operation and continued taking it every 6 hours postoperatively. In Pre-Naproxen group: patients received 500 mg Naproxen 30 minute before surgery and continued taking it every 8 hours postoperatively. In Naproxen group: patients received 500 mg Naproxen immediately after the operation and continued it every 8 hours postoperatively. An experienced surgeon operated for all of the patients.

Settings and conduct

The study was related to third molar teeth surgery which was conducted in Shiraz School of Dentistry. Patients who attended this center for third molar surgery were asked to voluntarily participate in the study. The patient was blind by covering the capsules

Participants/Inclusion and exclusion criteria

all of the patients signed an informed consent before their participation in the study. All of the patients had an impact mandibular third molar and were in ASA 1 category. All impact teeth were in level A and class 1 according to Pell and Gregory classification. None of the patients received analgesic medication at least 12 hours before the surgery. Exclusion criteria were any condition which contraindicated the use of NSAIDs, such as pregnancy, known allergy to NSAIDs, any drugs interaction, active ulceration or gastrointestinal bleeding, liver dysfunction, inflammatory intestinal disease, kidney dysfunction, or any psychological disorders.

Intervention groups

Pain intensity after lower third molar surgery between those who have received Gelofen compared to those

received Naproxen

Main outcome variables

Pain intensity after the surgery

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180330039161N1**

Registration date: **2018-09-10, 1397/06/19**

Registration timing: **retrospective**

Last update: **2018-09-10, 1397/06/19**

Update count: **0**

Registration date

2018-09-10, 1397/06/19

Registrant information

Name

Saeid Tavanafar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3230 6655

Email address

Tavanafar@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-09-23, 1396/07/01

Expected recruitment end date

2017-12-16, 1396/09/25

Actual recruitment start date

2017-07-05, 1396/04/14

Actual recruitment end date

2017-09-21, 1396/06/30

Trial completion date

empty

Scientific title

Comparison of Naproxen and Gelofen for Pain Relief in the Third Molar Surgery:A single-blind randomized clinical trial study

Public title

Different pain killer for third molar surgery

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

an impact mandibular third molar ASA 1 category level A and class 1 according to Pell and Gregory classification
No analgesic medication at least 12 hours before the surgery

Exclusion criteria:

pregnancy known allergy to NSAIDs drugs interaction
active ulceration or gastrointestinal bleeding liver dysfunction inflammatory intestinal disease kidney dysfunction psychological disorders

Age

No age limit

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **20**

Actual sample size reached: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

block individual table randomization

Blinding (investigator's opinion)

Single blinded

Blinding description

Both medication had similar capsules

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

none

Secondary trial Id

none

Registration date

2017-12-11, 1396/09/20

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciences

Street address

Qom Abad, Ghasrodasht Street

City

Shiraz

Province

Fars

Postal code

7134647379

Approval date

2017-04-09, 1396/01/20

Ethics committee reference number

IR.SUMS.REC.1396.122

Health conditions studied

1

Description of health condition studied

Pain after lower third molar surgery

ICD-10 code

G89.1

ICD-10 code description

Acute pain, not elsewhere classified

Primary outcomes

1

Description

Pain intensity after third molar surgery

Timepoint

pain intensity at 2, 6, 12 and 24 hours after intervention

Method of measurement

visual analogue scale to measure pain

Secondary outcomes

1

Description

none

Timepoint

none

Method of measurement

none

Intervention groups

1

Description

Control group: 400 mg Gelofen immediately after third molar surgery and continuing every 6 hours

Category

Treatment - Drugs

2

Description

Intervention group 1: 400 mg Gelofen 30 minute pre-operative and continuing every 6 hours,

Category

Treatment - Drugs

3

Description

Intervention group 2: 500 mgNaproxen 30 minute pre-operative and every 8 hours

Category

Treatment - Drugs

4

Description

Intervention group 3: 500mg Naproxen immediately postoperative and every 8 hours

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

School of Dentistry, Shiraz University of Medical Sciences

Full name of responsible person

Mehdi Hayati

Street address

Ghasrodasht street, Gomabad District

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tavanafar@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz 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

Shiraz University of Medical Sciences

Proportion provided by this source

10

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

Shiraz University of Medical Sciences

Full name of responsible person

Saeid Tavanafar

Position

Resident

Latest degree

Specialist

Other areas of specialty/work

Oral and Maxillofacial Surgery

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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

IPD collected for the primary outcome measure only

When the data will become available and for how long

starting 6 months after publication

To whom data/document is available

only available for people working in academic institutions

Under which criteria data/document could be used

For scientific researches and only for academic staff

From where data/document is obtainable

by Email to : "s.tavanafar@gmail.com" or
"tavanafar@sums.ac.ir"

What processes are involved for a request to access data/document

Within a week

Comments