Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mehdi Hayati
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7134647379
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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
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Person responsible for updating data

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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