Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparison of the effect of topical and oral ibuprofen on pain relief after mandibular third incisor surgery

Protocol summary

Study aim
What is the difference between topical and oral ibuprofen in pain control in terms of pain intensity and duration of analgesia?
Design
Clinical trial, randomized to 20 patients
Settings and conduct
Department of Surgery, School of Dentistry, Islamic Azad University. Divided into 2 groups of 10 people. In the first group, the patient is placed in a semi-supine position. After anesthesia, incision, and removal of the flap with a surgical milling, some of the bone covering the tooth is removed and after the tooth section and extraction. The area is rinsed, then the ibuprofen 400mg tablet is divided into several parts and placed with gelfoam as a carrier of ibuprofen inside the extracted tooth socket. Second group: The second group is given ibuprofen 400 mg orally 20 minutes before impacted wisdom tooth surgery.
Participants/Inclusion and exclusion criteria
Be in the age range of 18 to 35 and have the indication for surgery to extract the wisdom tooth of the mandible. Systemic disease for exclusion.
Intervention groups
Intervention group: Evaluation of the effectiveness of topical ibuprofen on reducing pain after impacted wisdom tooth surgery Control group: Evaluation of the effectiveness of oral ibuprofen on reducing pain after impacted wisdom tooth surgery
Main outcome variables
Pain

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20210501051150N1**
Registration date: **2021-05-31, 1400/03/10**
Registration timing: **prospective**
Last update: **2021-05-31, 1400/03/10**
Update count: **0**
Registration date
2021-05-31, 1400/03/10

Registrant information
Name
Fatemeh Azimifard
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 21 2206 9849
Email address
arbehnaz@yahoo.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-06-15, 1400/03/25
Expected recruitment end date
2021-10-02, 1400/07/10
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of topical and oral ibuprofen on pain relief after mandibular third incisor surgery

Public title
The effect of topical and oral ibuprofen on pain relief
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Indications for surgical extraction of mandibular wisdom

teeth

Exclusion criteria:

systemic disease

Age

From **18 years** old to **35 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, use a simple random dedicated method to help the computer. In this method, a list of numbers from 1 to 20 is prepared. Randomly lists this list called numbers. Depending on the time of your entry into the surgical department of the School of Dentistry, another of these numbers is assigned to the patient and based on the list in the list is available to the intervention group (subject that ibuprofen is associated with jelfoam) and the control group (group that ibuprofen Produces food) is allocated.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

In one group, oral ibuprofen is used and in the other group, topical ibuprofen is used with the same condition as the patients.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of AZAD University of dental Sciences

Street address

Aseman12 shargi , paknezhad, و saadat abad ,

City

tehran

Province

Tehran

Postal code

1998181887

Approval date

2021-01-27, 1399/11/08

Ethics committee reference number

IR.IAU.DENTAL.REC.1399.266

Health conditions studied

1

Description of health condition studied

Impacted tooth

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

pain intensity

Timepoint

Measurement of pain before the intervention and up to 12 hours after the intervention.

Method of measurement

visual analogue scale for pain

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: After surgery and extraction of the impacted wisdom tooth, ibuprofen has divided 400 mg into several parts and put it with gelfoam in socket.

Category

Treatment - Other

2

Description

Control group: Ibuprofen 400 mm is given orally to patients 20 minutes before surgery.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

University Hospital Azad Islamic

Full name of responsible person

Fatemeh Azimi Fard

Street address

Tehran Province, Tehran, Pasdaran Ave

City

Tehran

Province

Tehran

Postal code

1946853314

Phone

+98 21 2256 4571

Email

arbehnaz@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

DR. Arash Azizi

Street address

No. 9, Pasdaran St., 9th Neystan

City

Tehran

Province

Tehran

Postal code

1946853314

Phone

+98 21 2256 4571

Email

arbehnaz@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

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

Islamic Azad University

Full name of responsible person

Hossein Tafzali Shadpour

Position

Associate professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

Street address

No. 9, Pasdaran St., 9th Neystan

City

Tehran

Province

Tehran

Postal code

1946853314

Phone

+98 21 2256 4571

Email

arbehnaz@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Fatemeh Azimi Fard

Position

Dentist

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

Street address

Aseman12 shargi , Paknezhad, و Saadat abad

City

Tehran

Province

Tehran

Postal code

1998181887

Phone

009822069849

Email

arbehnaz@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Islamic Azad University

Full name of responsible person

Fatemeh Azimifard

Position

Dentist

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

Street address

Aseman12 shargi , Paknejad, و Saadat abad

City

Tehran

Province

Tehran

Postal code

1998181887

Phone

+98 21 2206 9849

Email

arbehnaz@yahoo.com

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
Upon completion of the study, confidential information such as patient details, etc. will be deleted and other information will be provided to researchers.

When the data will become available and for how long
One year

To whom data/document is available
All dentist student

Under which criteria data/document could be used
Information on the outcome and pain pressure can be distributed in this study

From where data/document is obtainable
1. Library of the School of Dentistry of Tehran Azad University Phone 02122006660 Postal Code 1916393813
2. fatemeh.azimifard@gmail.com
3.arbehnaz@yahoo.com

What processes are involved for a request to access data/document
1. An official request or a letter from the library of the School of Dentistry of the Azad University can use all the information as soon as possible. 2. The request can be accessed through the mentioned e-mail address within ten days fatemeh.azimifard@gmail.com

Comments