

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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, 9 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**

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**Postal code**

1946853314

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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

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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**

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

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## 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

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## Person responsible for updating data

#### Contact

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**Full name of responsible person**

Fatemeh Azimifard

**Position**

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**Latest degree**

A Level or less

**Other areas of specialty/work**

Dentistry

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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

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