

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jul 2026

### Comparison of the efficacy of oxycodone with Acetaminophen codeine on pain control after erupted mandibular third molar extraction.

#### Protocol summary

##### Study aim

Determining the effect of Oxycodone in comparison with Acetaminophen codeine on pain control after removal of the grown mandibular third molar.

##### Design

Randomized, double blinded clinical trial with a parallel group design of 48 patients. Sealed envelopes were used for randomization.

##### Settings and conduct

Eligible patients were operated on by a surgeon to extract the third erupted mandibular molar. Patients were randomly divided into two groups and the pill was given blindly by the surgeon. The time of receiving the studied analgesics is one hour before the surgery and after observing the first sign of pain. This trial was performed in the Department of Oral and Maxillofacial Surgery, School of Dentistry, Islamic Azad University of Medical Sciences, Tehran.

##### Participants/Inclusion and exclusion criteria

Admission requirements: 1. Patients with third erupted molar under the same conditions. 2. Patients in the age range of 17 to 35 years. No entry conditions: 1. Systemic disease. 2. Menstruation, pregnancy or breastfeeding. 3. Pain in other parts of the body or primary pain in third molar. 4. taking analgesic less than 48 hours before. 5. Taking another analgesic at the same time.

##### Intervention groups

The intervention group in this study is a group in which patients are given 5 mg of Oxycodone to evaluate the effect of this drug on pain control after extraction of the third molars of the mandible compared to the Acetaminophen codeine 300/20 mg.

##### Main outcome variables

Pain intensity, Duration of analgesia

#### General information

##### Reason for update

##### Acronym

#### IRCT registration information

IRCT registration number: **IRCT20171216037893N4**

Registration date: **2021-01-26, 1399/11/07**

Registration timing: **retrospective**

Last update: **2021-01-26, 1399/11/07**

Update count: **0**

#### Registration date

2021-01-26, 1399/11/07

#### Registrant information

##### Name

Hamidreza Mahaseni aghdam

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 2240 6440

##### Email address

h\_mahaseni@dentaliau.ac.ir

#### Recruitment status

**Recruitment complete**

#### Funding source

#### Expected recruitment start date

2020-12-08, 1399/09/18

#### Expected recruitment end date

2021-01-09, 1399/10/20

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Comparison of the efficacy of oxycodone with Acetaminophen codeine on pain control after erupted mandibular third molar extraction.

## Public title

Comparison of the efficacy of Oxycodone with Acetaminophen codeine on pain control after extraction of wisdom teeth.

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients with erupted mandibular third molar Age range: 17 to 35 years

### Exclusion criteria:

systemic disease Menstruation, pregnancy and breastfeeding Pain in other parts of the body or primary toothache Taking painkillers less than 48 hours before Take another painkiller at the same time as the medication

## Age

From **17 years** old to **35 years** old

## Gender

Both

## Phase

3

## Groups that have been masked

- Participant
- Care provider

## Sample size

Target sample size: **48**

## Randomization (investigator's opinion)

Randomized

## Randomization description

Patients are randomly considered as both intervention and control groups. Simple random individually with using random numbers. In this way, the referring patients receive the number assigned, the patients receive the even number of drug number 1 and the patients receive the odd number of drug number 2, respectively.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

The researcher delivers painkillers in sealed bags to the clinical caregiver. Study participants receive an anonymous and sealed analgesic from the clinical caregiver after tooth extraction.

## 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 University of Medical Sciences, Tehran

#### Street address

Dental College, 9th Neyestan Ave, Pasdaran st.

#### City

Tehran

#### Province

Tehran

#### Postal code

1946853314

#### Approval date

2020-12-07, 1399/09/17

#### Ethics committee reference number

IR.IAU.DENTAL.REC.1399.240

## Health conditions studied

### 1

#### Description of health condition studied

Extraction of the third erupted mandibular molar

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Intensity of pain

#### Timepoint

After 24 hours

#### Method of measurement

Visual Analogue Scale

### 2

#### Description

Duration of analgesia after taking analgesic

#### Timepoint

After 24 hours

#### Method of measurement

the watch

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: This group takes a dose of 5 mg Oxycodone one hour before surgery and also the next dose after feeling the first pain after tooth extraction.

#### Category

Treatment - Drugs

### 2

#### Description

Control group: This group takes a dose of 300/20 mg Acetaminophen codeine one hour before surgery and also the next dose after feeling the first pain after tooth extraction.

**Category**

Treatment - Drugs

**Recruitment centers**

1

**Recruitment center**

**Name of recruitment center**

Oral and Maxillofacial Surgery department, School of Dentistry, Islamic Azad University of Medical S

**Full name of responsible person**

Hamidreza Mahaseni Aghdam

**Street address**

Dentistry department, 9th Neyestan Ave., Pasdaran St.

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+98 21 2256 4571

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hamidmahaseni@gmail.com

**Sponsors / Funding sources**

1

**Sponsor**

**Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Arash Azizi

**Street address**

Dentistry college, 9th Neyestan Ave., Pasdaran St.

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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**

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**

Tehran University of Medical Sciences

**Full name of responsible person**

Hamidreza Mahaseni Aghdam

**Position**

Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dentistry

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**Person responsible for scientific inquiries**

**Contact**

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Tehran University of Medical Sciences

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## Person responsible for updating data

hamidmahaseni@gmail.com

### Contact

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Tehran University of Medical Sciences

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**Email**

## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not a plan to make this available

**Informed Consent Form**

Undecided - It is not yet known if there will be a plan to make this available

**Clinical Study Report**

Undecided - It is not yet known if there will be a plan to make this available

**Analytic Code**

Undecided - It is not yet known if there will be a plan to make this available

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available