

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

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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

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Arash Azizi

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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

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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