Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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)

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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
Ffter 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

Dentistry

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Person responsible for updating data

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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