Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Aug 2026

Comparing effects of local injection of bupivacaine with and without fentanyl at the site of surgery in open reduction mandibular surgeries on acute pain intensity and opioid requirement: a randomized clinical trial

Protocol summary

Study aim

Comparing effects of local injection of bupivacaine with and without fentanyl at the site of surgery in open reduction mandibular surgeries on acute pain intensity and opioid requirement: a randomized clinical trial.

Design

A clinical trial with a parallel intervention group, double-blind, randomized, phase two on 44 patients. The sampling method is random. Randomization using a table of random numbers is Random allocation software.

Settings and conduct

Among the patients referred to Maxillofacial Surgery Department of Imam Reza Tabriz Hospital, who are candidates for open surgery for isolated mandibular fracture, participate in the study. Patients are randomly assigned to one of the groups. In the control group, after the surgery and after the sutures, 2 cc of bupivacaine 0.5% (5mg/ml) solution and in the intervention group 2cc of bupivacaine 0.5% (5mg/ml) solution along with 25 micrograms of fentanyl in the surgical site. After discharge from recovery, patients' pain will be measured every four hours for 24 hours using a ten-point VAS scale. The patient is aware of the existence of two types of treatment, but he does not know which group he is in. The data importers in the relevant checklist are not aware of the type of intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Patients who are candidates for open mandibular surgery, except for comminuted and condylar fractures, Surgery performed by one person, ASA class one and two patients Exclusion criteria: The occurrence of any complications that prevent participation in the study, Hypersensitivity to fentanyl, bupivacaine, and other drugs, The presence of infection in the operation site

Intervention groups

Intervention: bupivacaine injection with fentanyl after surgery Control: bupivacaine injection without fentanyl after surgery

Main outcome variables

The amount of pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220727055567N1**
Registration date: **2022-08-12, 1401/05/21**
Registration timing: **registered_while_recruiting**

Last update: **2022-08-12, 1401/05/21**
Update count: **0**

Registration date

2022-08-12, 1401/05/21

Registrant information

Name

Vahid Baybourdi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 914 245 4919

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baybourdi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-03, 1401/05/12

Expected recruitment end date

2022-08-30, 1401/06/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing effects of local injection of bupivacaine with and without fentanyl at the site of surgery in open reduction mandibular surgeries on acute pain intensity and opioid requirement: a randomized clinical trial

Public title

The effect of fentanyl in reducing pain after jaw surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Candidate patients for open mandibular surgery Age above 18 years Duration of surgery less than 4 hours Candidate patients for general anesthesia Consent to jaw fixation

Exclusion criteria:

Unwillingness to cooperate in the study The occurrence of any complications that prevent participation in the study Hypersensitivity to fentanyl, bupivacaine, and other drugs The patient's lack of satisfaction with intermaxillary fixation after the operation Existence of underlying disease and confounding factor such as: hemorrhagic diseases and coagulopathy, kidney and liver diseases, mental and neurological diseases, obstructive lung diseases, hemostatic disorders and dialysis in patients Addiction to drugs and psychoactive substances and history of drug abuse The presence of infection in the operation site History of taking antidepressants and sedatives and any medicine that changes the perception of pain

Age

From **18 years** old

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **44**

Randomization (investigator's opinion)

Randomized

Randomization description

Random sampling will be done among the patients referred to the maxillofacial surgery department of Imam Reza Hospital in Tabriz who is eligible for the study. The randomization method is simple and its unit is the individual. Our tool for randomizing is the random number table. Accordingly, the type of treatment is marked with the code A (bupivacaine with fentanyl) and B (bupivacaine without fentanyl) and will be placed inside the sealed envelopes; Then the envelopes will be placed in a bag and mixed. After that, it will be randomly chosen from the bag and upon viewing the code, the treatment will be given to the patient. None of the patients will be informed about the treatment of another patient.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study is double-blind, so patients do not know which group they will be in. The researcher who must enter data into the checklist will not know which intervention was conducted. Patients are aware of the existence of two types of treatment, but they do not know which group they belong to.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

کمیته اخلاق دانشگاه علوم پزشکی تبریز

Street address

Golgasht St., Tabriz University of Medical Sciences

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Approval date

2022-06-27, 1401/04/06

Ethics committee reference number

IR.TBZMED.REC.1401.307

Health conditions studied

1

Description of health condition studied

Fracture of mandible

ICD-10 code

S02.6

ICD-10 code description

Fracture of mandible

Primary outcomes

1

Description

The amount of pain

Timepoint

Every four hours for 24 hours after surgery

Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
The amount of opioid use
Timepoint
Every four hours for 24 hours after surgery
Method of measurement
After surgery, the pain level is measured every four hours for 24 hours. If VAS is higher than 5, Pethidine (Exir Company-Iran) will be injected intramuscularly at the rate of 1 mg/kg. After four hours, if the pain repeats, Pethidine injection at the rate of 1 mg/kg will be repeated. The number of times the patient needs pethidine in twenty-four hours will be recorded.

Intervention groups

1

Description
Intervention group: After the surgery is completed and the sutures are applied, 2 cc of Bupivacaine solution (Exir Company-Iran) 0.5% (5 mg/ml) along with 25 micrograms of fentanyl routinely used in the hospital will be injected into the surgical site through an insulin syringe. After discharge from recovery, patients' pain will be measured by a ten-point VAS scale for 24 hours every four hours. Also, the amount of opioid medication needed based on milligrams of pethidine will also be recorded for patients. If the pain intensity of the patients is higher than 5, pethidine will be injected intramuscularly at the rate of 1 mg/kg.
Category
Treatment - Drugs

2

Description
Control group: After the surgery is completed and the sutures are applied, 2 cc of Bupivacaine solution (Exir Company-Iran) 0.5% (5 mg/ml) will be injected into the surgical site by an insulin syringe. After discharge from recovery, patients' pain will be measured by a ten-point VAS scale for 24 hours every four hours. Also, the amount of opioid medication needed based on milligrams of pethidine will also be recorded for patients. If the pain intensity of the patients is higher than 5, pethidine will be injected intramuscularly at the rate of 1 mg/kg.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza Hospital in Tabriz
Full name of responsible person
Saeed Nezafati
Street address
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nezaf2000@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Mojgan Kachoei
Street address
Golgasht St., Tabriz University of Medical Sciences
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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
Tabriz University of Medical Sciences
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
Tabriz University of Medical Sciences
Full name of responsible person

Saeed Nezafati

Position
Professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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

Statistical Analysis Plan
Not applicable

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
Not applicable

Data Dictionary
Not applicable