Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluation the effect of Carbomer based Bupivacaine hydrogel on post-operation pain in impacted mandibular wisdom tooth

Protocol summary

Study aim
The purpose of our study is to investigate the effect of bupivacaine hydrogel based on carbomer on the pain of patients after mandibular wisdom tooth surgery and their painkiller usage

Design
A randomized clinical trial, split mouth method, triple blinded, phase 2 on 16 patients, block randomization method

Settings and conduct
The study is conducted on patients referred to the clinic of Qazvin Dental Faculty, before that the patients are informed and if they fill consent, they will enter the study. The tooth on one side of the patient is randomly selected by a third person and extracted by a maxillofacial surgeon. 1 cc of the drug/placebo hydrogel (A or B) which has already been determined by the randomized block method is placed and closed with suture. The patient is evaluated in time intervals in terms of the number of painkillers and post-op pain. In this study, the evaluator, the statistical analyst and the patient are blinded.

Participants/Inclusion and exclusion criteria
16 patients referred to the clinic of Qazvin Dental Faculty Inclusion criteria: Patients with impacted mesioangular mandibular wisdom teeth class B and C of Pell and Gregory classification Growth of at least 1/2 to 2/3 of the wisdom tooth root Not taking any opioid or non-steroidal pain medication continuously Absence of systemic disease Non-entry criteria: Patients with other than mesioangular depression and other Pell and Gregory classes Continuous use of opioid and non-steroidal pain medications The presence of any systemic disease Allergy to bupivacaine or carbomer

Intervention groups
Our study includes investigating the effect of carbomer-based bupivacaine hydrogel placed in socket on post-op pain and number of painkiller used. The control group also receives placebo hydrogel based on carbomer.

Main outcome variables
post-op pain, number of painkillers used

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20221201056682N1**
Registration date: **2023-07-17, 1402/04/26**
Registration timing: **prospective**

Last update: **2023-07-17, 1402/04/26**
Update count: **0**

Registration date
2023-07-17, 1402/04/26

Registrant information

Name
Erfan Khorasani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 28 3337 4217

Email address
e.khorasani@qums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-09-10, 1402/06/19

Expected recruitment end date
2024-03-17, 1402/12/27

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation the effect of Carbomer based Bupivacaine hydrogel on post-operation pain in impacted mandibular wisdom tooth

Public title
Effect of Bupivacaine hydrogel on post-operation pain in impacted wisdom tooth

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
patients with impacted mesioangular mandibular wisdom teeth class B and C of Pell and Gregory classification Growth of at least 1/2 to 2/3 of the wisdom tooth root
Exclusion criteria:
Patients with other than mesioangular depression and other Pell and Gregory classes Continuous use of opioid and non-steroidal pain medications The presence of any systemic disease Allergy to bupivacaine or carbomer

Age
From **18 years** old

Gender
Both

Phase
2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size
Target sample size: **16**
More than 1 sample in each individual
Number of samples in each individual: **2**
The sampling method is split mouth, in which one patient's tooth on one side is randomly selected during surgery by another person, and the desired hydrogel (A or B) is used. In the next surgery, the other tooth is treated with another hydrogel.

Randomization (investigator's opinion)
Randomized

Randomization description
Patients' teeth are allocated to two treatment groups A and B using the method of random blocks (Balance block randomization), the size of each block is 4 and the total number of blocks is 4 as described in the attached table. The method of allocation of balanced randomization for participants in a randomized controlled clinical trial study is the effect of hydrogel containing bupivacaine based on carbomer (group A) and placebo hydrogel (group B) in reducing mandibular wisdom tooth surgery. block identifier block size sequence within block treatment 1 4 1 Group A 1 4 2 Group A 1 4 3 Group B 1 4 4 Group B 2 4 1 Group A 2 4 2 Group B 2 4 3 Group A 2 4 4 Group A 3 4 1 Group B 3 4 2 Group A 3 4 3 Group A 3 4 4 Group B 4 4 1 Group A 4 4 2 Group A 4 4 3 Group B 4 4 4 Group B

Blinding (investigator's opinion)
Triple blinded

Blinding description
The sampling method is split mouth, in which one patient's tooth on one side is randomly selected during surgery by another person, and the desired hydrogel (A or B) is used. The patient does not know which of the hydrogels has been used in his mouth. Also, the outcome assessor is uninformed. The statistical analyzer does not know the type of hydrogel and groups.

Placebo
Used

Assignment
Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research Ethics committee of Qazvin university of medical sciences

Street address
Research and Technology Deputy, 1st sub-district, Mavedat Alley, Beheshti Blvd, Qazvin

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Province
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Postal code
3415613911

Approval date
2023-07-12, 1402/04/21

Ethics committee reference number
IR.QUMS.REC.1402.102

Health conditions studied

1

Description of health condition studied
post operation pain

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
patient's post operation pain scale

Timepoint
measure pain in 2, 6, 12, 24, 48 and 72 hours after surgery

Method of measurement
Visual Analogue Scale

Secondary outcomes

1

Description
painkiller usage
Timepoint
2, 6, 12, 24, 48 and 72 hours after surgery
Method of measurement
self statement

Intervention groups

1

Description
Intervention group: Carbomer-based hydrogel was prepared by the pharmaceutical department of Shahid Beheshti Faculty of Pharmacy with a ratio of 7.5 mg/cc of the active ingredient in antiseptic conditions with sterile materials, and after the completion of the manufacturing process, the hydrogel was poured into sterile falcon tubes and sterilized by gamma radiation. and finally its lid is sealed with cellulose until consumption. The hydrogel containing bupivacaine is measured using a spectrophotometer to measure the release rate of the drug at zero, 40 minutes, 24 and 48 hours. In wisdom tooth surgery, before starting, the patient's pain level, if any, is stated and marked on the VAS chart. Then the inferior alveolar nerve (IAN) block injection will be done using 3% prilocaine and directly. Long buccal injection is also performed using 2% lidocaine. Then, after 10 minutes, a pocket-shaped flap is cut from the mesial of the first molar on the buccal side to the beginning of the ramus, and the flap is gently separated from the bone using a periosteal elevator. By removing the bone around the tooth if needed and sectioning the tooth using a round and fissure bur, we remove the tooth in several parts using an elevator. Then we curettage the sac and wash it with normal saline and put 1 cc of hydrogel containing bupivacaine in the sac and sew it with 4 zero polyglycolic acid (P.G.A) thread. We prescribe antibiotics metronidazole 250 mg (1 tablet every 8 hours) and amoxicillin 500 mg (1 tablet every 8 hours) to the patients. Also, the patient is told to take ibuprofen 400 mg in case of pain.
Category
Treatment - Drugs

2

Description
Control group: Placebo hydrogel based on carbomer was prepared by the Pharmaceuticals Department of Shahid Beheshti Faculty of Pharmacy in antiseptic conditions with sterile materials and after the completion of the manufacturing process, the hydrogel was poured into sterile falcon tubes and sterilized with gamma rays and finally closed with cellulose. It is sealed until consumption. In wisdom tooth surgery, before starting, the patient's pain level, if any, is stated and marked on the VAS chart. Then the inferior alveolar nerve (IAN) block injection will be done using 3% prilocaine and directly. Long buccal injection is also performed using 2% lidocaine. Then, after 10 minutes, a pocket-shaped flap is cut from the mesial of the first molar on the buccal side to the beginning of the ramus, and the flap is gently separated from the bone using a periosteal elevator. By removing the bone around the tooth if needed and sectioning the tooth using a trend and fissure bur, we remove the tooth in several parts using an elevator. Then we curettage the sac and wash it with normal saline and place 1 cc of placebo hydrogel in the sac and suture it with 4 zero polyglycolic acid (P.G.A) thread. We prescribe antibiotics metronidazole 250 mg (1 tablet every 8 hours) and amoxicillin 500 mg (1 tablet every 8 hours) to the patients. Also, the patient is told to take ibuprofen 400 mg in case of pain.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Qazvin dental school
Full name of responsible person
Erfan Khorasani
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Sponsors / Funding sources

1

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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

Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Erfan Khorasani

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Assistant professor

Latest degree

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Erfan Khorasani

Position

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Latest degree

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Other areas of specialty/work

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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

The data includes non-identifiable information of the patients such as gender, age, VAS data about the patients' pain and the number of painkillers they take. Also, the details of the hydrogel production can be provided and shared if the conditions mentioned below are followed.

When the data will become available and for how long

Access to study data begins 3 months after publication of results

To whom data/document is available

The data will be available to researchers working in academic and scientific institutions.

Under which criteria data/document could be used

The given data can be used for any statistical analysis, but the use of the hydrogel formulation data for manufacturing or commercialization depends on informing the researchers of this study.

From where data/document is obtainable

In order to access the data, they can contact Mr. Erfan Khorasani and the email mentioned below.
e.khorasani@qums.ac.ir

What processes are involved for a request to access data/document

After mentioning the details of data usage by the requester and also providing valid identification information, within one week to ten working days, the data will be provided to them via email.

Comments