

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the Effect of Topical Dexamethasone Injection with Rinsing of Extraction Sockets with Dexamethasone in Reducing Pain after Impacted Mandibular Third Molars

Protocol summary

Study aim

Comparison of the effect of topical injection of dexamethasone and rinsing of extracted teeth with dexamethasone and non-use of dexamethasone in Reduction of pain after impacted third molar of lower jaw

Design

A control trial with a control group, with parallel groups, blinded postoperative care and outcome assessment, randomized, phase 4 on 114 patients was used for randomization from www.randomizer.org

Settings and conduct

A clinical trial consisted of 114 patients referred to Bushehr Dental Clinic with impacted third molars in the mandible on each side (right or left). Patients are divided into 3 groups. Each group includes 38 patients. Before starting work, patients take a panoramic radiograph to examine the location of the tooth, their angle and mandibular nerve involvement, and The criteria for entry and exit criteria are approved. After surgery, the tissues of the dental follicle are removed. In one group of patients, after surgery, rinsing is performed with 50 cc of normal saline and finally the socket of extracted tooth is rinsed with dexamethasone. In the second group, after surgery and removal of follicular tissues, the socket is rinsing with 50cc of normal saline. After that, it is sutured and finally injected in the trygomandibular space. In the third group (control) after surgery and removal of follicular tissues, the socket is rinsing with 50cc of normal saline.

Participants/Inclusion and exclusion criteria

Age over 18 years and absence of uncontrolled systemic disease and low impacted wisdom teeth with mesioangular angle

Intervention groups

1. Intramuscular injection of dexamethasone 2. rinsing with dexamethasone 3. Do not inject dexamethasone

Main outcome variables

pain Trismus Inflammation swelling

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201101049209N2**

Registration date: **2020-11-18, 1399/08/28**

Registration timing: **registered_while_recruiting**

Last update: **2020-11-18, 1399/08/28**

Update count: **0**

Registration date

2020-11-18, 1399/08/28

Registrant information

Name

Milad Parvin

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 77 3542 8269

Email address

m.parvin@bpums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-10-29, 1399/08/08

Expected recruitment end date

2020-11-28, 1399/09/08

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the Effect of Topical Dexamethasone Injection with Rinsing of Extraction Sockets with Dexamethasone in Reducing Pain after Impacted Mandibular Third Molars

Public title

Dexamethasone Effect on Pain Reduction and Swelling after Surgery in the Lower Jaw

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

Over 18 years old No pericoronitis Absence of uncontrolled systemic disease Impacted Third molar of mandible with mesioangular angle

Exclusion criteria:

Age

From **18 years** old to **25 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **114**

Randomization (investigator's opinion)

Randomized

Randomization description

.For segmentation of patients into three groups of 38 (group A)and the silent rinsing of extracted teeth with dexamethasone (Group B)and Do not prescribe dexamethasone (group C), the Permuted Block randomization method has been used as block size of 6 blockate was used to create a balance in the number of samples allocated to each of the studied groups. the size of each block size method is used. The random layout was created using the free website Randomization.com (<http://randomization.com>). From the order of the Permuted Table Randomization and the arrival of the participants to study the only surgeon, the assessor should not be aware of any intervention that takes place for the individual and the block size. Thus, the allocation of data will remain hidden by the end of the study. That way, each participant will be assigned to the intervention or control groups and perform the expected process by the surgeon.

Blinding (investigator's opinion)

Single blinded

Blinding description

the impact assessor is not aware of the intervention

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of University of Medical Science
Bushehr University of Medical Sciences

Street address

Salman Farsi

City

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Province

Boushehr

Postal code

7518759577

Approval date

2020-10-27, 1399/08/06

Ethics committee reference number

IR.BPUMS.REC.1399.117

Health conditions studied

1

Description of health condition studied

pain and swelling

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Patients' pain

Timepoint

at times, 2 hours after surgery, 6 hours after surgery, 24 hours after surgery, 72 hours after surgery, and finally 7 days after surgery

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Trismus

Timepoint

at times, before surgery, after surgery and on the first, third and seventh days.

Method of measurement

measuring the distance between the incisal edge at the opening of the mouth and with a caliper device in

millimeters

Intervention groups

1

Description

Intervention group: Receive dexamethasone by injection into the trygmandibular space

Category

Treatment - Drugs

2

Description

Intervention group: rinsing the socket of extracted teeth with dexamethasone

Category

Treatment - Drugs

3

Description

Control group: Do not take dexamethasone

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

dental clinic of Bushehr University of Medical Sciences

Full name of responsible person

Amir Gorre

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Boushehr University of Medical Sciences

Full name of responsible person

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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

Boushehr University of Medical Sciences

Proportion provided by this source

10

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

Boushehr University of Medical Sciences

Full name of responsible person

Hassan Barbarz

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Full name of responsible person

Milad Parvin

Position

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Person responsible for updating data

Contact

Name of organization / entity
Boushehr University of Medical Sciences
Full name of responsible person
Hassan Barbarz
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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

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

Title and more details about the data/document

The data is numbered from one to ten and can be shared

When the data will become available and for how long

two months after the publication of the dissertation text

To whom data/document is available

every one

Under which criteria data/document could be used

Unconditional

From where data/document is obtainable

college

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

Request to Bushehr Dental School

Comments