

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Evaluation of the effects of using dexamethasone impregnated gel foam and local injection of Dexamethasone in reduction of post impacted third molar surgery side effects in patients referring to Bushehr University of Medical Sciences Dental clinic

Protocol summary

Study aim

Comparison of the effects of using dexamethasone-impregnated gel foam with topical injection of dexamethasone in reducing complications after impacted third molars

Design

A control trial with parallel groups, single blind, 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 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 desired tooth, their angle and in terms of mandibular nerve involvement, and to confirm the inclusion and exit criteria. After silent surgery, it is shortened if necessary and the tissues of the dental follicle are removed. In one group of patients, after surgery, the dexamethasone-impregnated foam gel is placed in silence and sutured. In the second group, after surgery and removal of follicular tissue, the silence is washed with 50 cc of normal saline. After that, it is sutured and finally injected in the trigomandibular space. In the third group (control) after surgery and removal of follicular tissues, the silent is washed with 50cc of normal saline and no corticosteroids, either as injections or gels. Dexamethasone-impregnated foam should not be used.

Participants/Inclusion and exclusion criteria

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

Intervention groups

Intervention group 1: Placing dexamethasone impregnated gel foam in the extracted socket.

Intervention group 2: intramuscular injection of dexamethasone. Intervention group 3: do not inject dexamethasone.

Main outcome variables

Pain; trismus; inflammation; swelling

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201101049209N1**

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

Registration timing: **prospective**

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)

Phone

+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

2020-11-28, 1399/09/08

Actual recruitment end date

2020-11-28, 1399/09/08

Trial completion date

2020-12-19, 1399/09/29

Scientific title

Evaluation of the effects of using dexamethasone impregnated gel foam and local injection of Dexamethasone in reduction of post impacted third molar surgery side effects in patients referring to Bushehr University of Medical Sciences Dental clinic

Public title

Evaluation of the effects of using Dexamethasone impregnated gel foam and local injection of Dexamethasone in reduction of post impacted third molar surgery side effects in patients referring to Bushehr University of Medical Sciences Dental clinic

Purpose

Supportive

Inclusion/Exclusion criteria**Inclusion criteria:**

Third molar of mandible(mesioangular) No pericoronitis
Absence of uncontrolled systemic disease Age older than 18 years old

Exclusion criteria:

Presence of peicoronitis Presence of uncontrolld systemic disease

Age

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

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **114**

Actual sample size reached: **114**

Randomization (investigator's opinion)

Randomized

Randomization description

114 patients from Patients referred to the Oral and Maxillofacial Surgery Department of Bushehr Dental Clinic Using Random Allocation Based random number from the randomizer.org website will fall into three groups

Blinding (investigator's opinion)

Double blinded

Blinding description

The participant, outcome assessor, and data analyst have no knowledge of the type of intervention performed.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Bushehr University of Medical Sciences

Street address

Bushehr University of Medical Sciences, Salman Farsi St.

City

Bushehr

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**

Post operative pain

ICD-10 code

K08.8

ICD-10 code description

Other specified disorders of teeth and supporting structures

2**Description of health condition studied**

Trismus

ICD-10 code

R25.2

ICD-10 code description

Cramp and spasm

Primary outcomes**1****Description**

Patients' pain

Timepoint

Baseline, 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

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Secondary outcomes**1****Description**

Trismus

Timepoint

Baseline, 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: Placement of dexamethasone-impregnated gelfoam

Category

Treatment - Drugs

3**Description**

Control group: Do not take dexamethasone

Category

N/A

Recruitment centers**1****Recruitment center****Name of recruitment center**

Dental clinic of Bushehr

Full name of responsible person

Nima Kamgar

Street address

Kuy-e-Bandar, Moallem St

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Boushehr

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7514633341

Phone

+98 77 3332 2081

Email**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Boushehr University of Medical Sciences

Full name of responsible person

Fatemeh Dehghan Azad

Street address

Imam Khomeini St., in front of Bahman movie theater

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Email

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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

Mohsen Salehi

Position

Student

Latest degree

A Level or less

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Boushehr University of Medical Sciences

Full name of responsible person

Milad Parvin

Position

Dentist

Latest degree

Specialist

Other areas of specialty/work

Oral and Maxillofacial Surgery

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Person responsible for updating data

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Full name of responsible person

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Latest degree

A Level or less

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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

All data can be shared after individuals are unidentifiable

When the data will become available and for how long

Access period is from the publication of the dissertation to 1 year after the publication of the dissertation

To whom data/document is available

Anyone can access the data.

Under which criteria data/document could be used

This data can be used for further research, provided the source is mentioned

From where data/document is obtainable

Vice Chancellor for Research, Bushehr University of Medical Sciences

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

Request to Bushehr Dental School

Comments