Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 gelfoam 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 dexamethason 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; truisms; 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)

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+98 77 3542 8269

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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 opreative 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

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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7514633341
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+98 77 3332 2081
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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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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

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Position
Dentist

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Specialist

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Oral and Maxillofacial Surgery

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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 unidentified

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