Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The Evaluation of the Local Effect of Dexamethasone on Reducing Pain and Swelling after Impacted Third Molar Surgery

Protocol summary

Study aim
The evaluation of the local dexamethasone effect on reducing pain and swelling to local use into third molar socket in mandibular impacted third molar surgery on patients referred to the Special Clinic of Shiraz Dental School.

Design
Clinical trial with control group, with parallel groups, random allocation using binary block division, double blind, second phase on 30 patients, the random allocation procedure is determined by the statistical consultant.

Settings and conduct
In this study, a clinical trial is performed on the patients referred to the Special Clinic of Shiraz Dental School and the patients are 18 to 30 years old who have bilateral mesioangular impacted third molar with similar clinical and radiographic condition after obtaining informed consent, randomly enter the study. In first tooth surgery, gelfoam impregnated with half vial of 4 gram dexamethasone Zahravi Pharmaceutical Company and in second surgery performed one week after the first surgery, gelfoam without dexamethasone is inserted into the socket of the extracted tooth and the area is sutured. 1, 3 and 10 days later, the swelling is measured with a white paper tape from the tragus to the corner of the lip and pain is measured by Visual Analog Scale Questionnaire. The patient and the person who measures pain and swelling are blinded in the study.

Participants/Inclusion and exclusion criteria
Participants: The patients with no immune system problems, with bilateral impacted mandibular third molars and age-group 18 to 30 years old. Participants not allowed: The patients with immune system problems, infection and aphthous after surgery.

Intervention groups
Immediately after surgery on both sides, randomly one side with dexamethasone-impregnated gelfoam and the other side are placed with gelfoam without dexamethasone.

Main outcome variables
Pain and swelling are assessed 1, 3 and 10 days later.

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220117053746N1**
Registration date: **2022-04-09, 1401/01/20**
Registration timing: **retrospective**

Last update: **2022-04-09, 1401/01/20**
Update count: **0**

Registration date
2022-04-09, 1401/01/20

Registrant information

Name
farhad ghorbani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 71 3626 3193

Email address
ghorbanif@sums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-02-19, 1400/11/30

Expected recruitment end date
2022-03-21, 1401/01/01

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Evaluation of the Local Effect of Dexamethasone on Reducing Pain and Swelling after Impacted Third Molar Surgery

Public title

The Evaluation of the Local Effect of Dexamethasone on Reducing Pain and Swelling after Impacted Third Molar Surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

No immune system problems Having third molar tooth located on both sides of mandible

Exclusion criteria:

Somebody has immune system problems Infection or aphthous in the mouth after surgery

Age

From **18 years** old to **30 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Not randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

The patient and the person who measures pain and swelling after treatment do not know what kind of treatment has been performed.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shiraz University of Medical Sciences

Street address

Shiraz Dental School, Ghasrodasht Street

City

Shiraz

Province

Fars

Postal code

7184836165

Approval date

2022-01-05, 1400/10/15

Ethics committee reference number

IR.SUMS.DENTAL.REC.1400.123

Health conditions studied

1

Description of health condition studied

Impacted Third Molar

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The amount of pain and swelling

Timepoint

1, 3 and 10 days later

Method of measurement

Pain based on VAS in range of 0 to 10 and swelling based on a white paper tape from the tragus to the corner of the lip are measured.

Secondary outcomes

1

Description

Pain

Timepoint

1, 3 and 10 days later

Method of measurement

Pain is measured by Visual Analog Scale Questionnaire.

2

Description

Swelling

Timepoint

1, 3 and 10 days later

Method of measurement

Swelling is measured with a white paper tape from the tragus to the corner of the lip.

Intervention groups

1

Description

Intervention Group: In one side, impregnated gelfoam with half of 4-gram vial of dexamethasone made in Zahravi Pharmaceutical Company is put inside the socket of extracted and impacted tooth.

Category
Treatment - Drugs

2

Description
Control Group: On the other side, gelfoam without dexamethasone is put inside the extracted and impacted tooth.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shiraz Dental School

Full name of responsible person
Farhad Ghorbani

Street address
Shiraz Dental School, Ghasrodasht Street

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz 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
Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
Farhad Ghorbani

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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Person responsible for updating data

Contact
Name of organization / entity
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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
No - There is not a plan to make this available
Statistical Analysis Plan
Undecided - It is not yet known if there will be a plan to make this available
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
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