

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Study of the effect of gelfoam impregnated with dexamethasone on swelling, bleeding, and pain after third molars of mandible surgery

Protocol summary

Study aim

The study of the effectiveness of gelfoam soaked in dexamethasone on bleeding, swelling and pain control after mandibular third molar surgery.

Design

This is a controlled single-blind split-mouth study conducted on 25 consecutive patients requiring surgical removal of bilateral mandibular impacted third molar.

Settings and conduct

This controlled single-blind split-mouth study conducted on 25 consecutive patients requiring surgical removal of bilateral mandibular impacted third molar referring to a private clinic of oral and maxillofacial surgery in Ahvaz in 2018. All the patients underwent routine dental extractions of mandibular molar teeth and randomly divided each side into two groups. In one side (intervention group), gelfoam soaked in dexamethasone (8 mg) was placed into the extraction socket postoperatively and the other side (control group) received no drug. For pain, swelling and bleeding evaluation, all patients were given a form to record visual analog scale (VAS) scores on the first, third and sixth day after surgery.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Age of 18 to 41 years, consent to participate in the study, patients requiring surgical removal of bilateral mandibular impacted third molar; Exclusion criteria: Taking corticosteroids, systemic disorders, acute infections.

Intervention groups

In the intervention group gelfoam soaked in dexamethasone (8 mg) was placed into the extraction socket and control group received no drug.

Main outcome variables

Severity of Pain, swelling and bleeding

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180716040491N1**

Registration date: **2018-07-23, 1397/05/01**

Registration timing: **retrospective**

Last update: **2018-07-23, 1397/05/01**

Update count: **0**

Registration date

2018-07-23, 1397/05/01

Registrant information

Name

Ali Bavarsad Shahri Pour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3333 3477

Email address

Bavarsad.a@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-09, 1397/01/20

Expected recruitment end date

2018-06-10, 1397/03/20

Actual recruitment start date

2018-04-14, 1397/01/25

Actual recruitment end date

2018-06-15, 1397/03/25

Trial completion date

empty

Scientific title

Study of the effect of gelfoam impregnated with dexamethasone on swelling, bleeding, and pain after third molars of mandible surgery

Public title

Effect of gelfoam impregnated with dexamethasone on postoperative complication

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Bilateral surgery of impacted third molars of mandible Class I and II of Pell and Gregory classification

Exclusion criteria:

Taking corticosteroids Systemic disorders Acute infections

Age

From **18 years** old to **41 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: **25**

Actual sample size reached: **25**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Single blinded

Blinding description

The patients did not know about type of treatment and grouping.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Ahvaz Jundishapur University of Medical Science

Street address

Jundishapur University of Medical Science, Golestan Blvd.

City

Ahvaz

Province

Khouzestan

Postal code

61355393

Approval date

2017-10-22, 1396/07/30

Ethics committee reference number

IR.AJUMS.REC.1397.008

Health conditions studied**1****Description of health condition studied**

Impacted mandibular third molar

ICD-10 code

K01.1

ICD-10 code description

Impacted teeth

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

Pain

Timepoint

First, third and sixth days after surgery

Method of measurement

Visual analog scale (VAS)

2**Description**

Swelling

Timepoint

First, third and sixth days after surgery

Method of measurement

Visual analog scale (VAS)

3**Description**

Bleeding

Timepoint

First, third and sixth days after surgery

Method of measurement

Visual analog scale (VAS)

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Gelfoam soaked in dexamethasone (8 mg)

Category

Treatment - Drugs

2**Description**

Control group: Routine treatment

Category

Treatment - Surgery

Recruitment centers

1

Recruitment center

Name of recruitment center

Private clinic of oral and maxillofacial surgery

Full name of responsible person

Dr. Saeed ShirAfkan

Street address

No 52, East Tohid Ave, Kianpars

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6135715794

Phone

+98 61 3336 7619

Email

Shirafkan.saeed79@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz 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

Ahvaz 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

Ahvaz University of Medical Sciences

Full name of responsible person

Dr. Saeed ShirAfkan

Position

Assistant Professor

Latest degree

Specialist

Other areas of specialty/work

Oral and Maxillofacial Surgery

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Position

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Latest degree

Specialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Ali Bavarsad Shahri Pour

Position

General Dentist

Latest degree

Medical doctor

Other areas of specialty/work

Dentistry

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

Study Protocol

Undecided - It is not yet known if there will be 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