Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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)

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+98 61 3333 3477

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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 imoregnated with dexamthasone 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 Sciense
Street address
Jundishapur University of Medical Sciense, 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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Sponsors / Funding sources

1

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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
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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