

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 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

Khuzestan

##### 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

**City**

Ahvaz

**Province**

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**Postal code**

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**Phone**

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**Email**

Shirafkan.saeed79@gmail.com

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Ahvaz University of Medical Sciences

**Full name of responsible person**

Dr. Saeed ShirAfkan

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Jundishapur University of Medical Sciences, Golestan Blvd.

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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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## Person responsible for scientific 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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## Person responsible for updating data

### Contact

**Name of organization / entity**

Ahvaz University of Medical Sciences

**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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**Email**

alibavarsadshahri@gmail.com

**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