

Clinical Trial Protocol

Iranian Registry of Clinical Trials

20 Jul 2026

Comparison between the effect of foam gel impregnated with dexamethasone and tranexamic acid on swelling, bleeding and pain after mandibular wisdom teeth surgery

Protocol summary

Study aim

Comparison between the effect of gelfoam impregnated with dexamethasone and tranexamic acid on swelling, bleeding and pain after mandibular wisdom teeth surgery

Design

Clinical trial with two intervention groups with one-sided blind parallel groups with phase 3 randomized table on 58 patients

Settings and conduct

58 patients referred to a private clinic located in Bandar Abbas city in 1401 with moderate severity of lower wisdom tooth surgery were divided into two groups of 29 patients, one group receiving dexamethasone and the other tranexamic acid. All surgeries will be performed by one surgeon using a single protocol. Then, on the first, third, and sixth days after surgery, the amount of pain, swelling, and bleeding is measured.

Participants/Inclusion and exclusion criteria

All patients aged 18-60 years of both sexes and without systemic problems Patients with mandibular third molar without pericoronitis and infection People in whom it is possible to measure and track pain, swelling and bleeding

Intervention groups

Patients in two groups of 29. The first group: using gelfoam impregnated with dexamethasone The second group: using gelfoam impregnated with tranexamic acid

Main outcome variables

Pain, swelling, and bleeding

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221226056929N1**

Registration date: **2022-12-29, 1401/10/08**

Registration timing: **prospective**

Last update: **2022-12-29, 1401/10/08**

Update count: **0**

Registration date

2022-12-29, 1401/10/08

Registrant information

Name

Fateme Zahmatkesh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 5364 5945

Email address

neda1223roz@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-01-10, 1401/10/20

Expected recruitment end date

2023-03-11, 1401/12/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison between the effect of foam gel impregnated with dexamethasone and tranexamic acid on swelling, bleeding and pain after mandibular wisdom teeth surgery

Public title

Investigating the effect of Gelfoam on reducing swelling, bleeding and pain after mandibular wisdom tooth surgery.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

All patients aged 18-60 years of both sexes and without systemic problems Patients with mandibular third molar without pericoronitis and infection People in whom it is possible to measure and track pain, swelling and bleeding.

Exclusion criteria:

Patient's unwillingness to cooperate Failure to strictly follow postoperative instructions Existence of systemic diseases and pregnant women The presence of infection in the patient Patients who have unusual problems during tooth extraction

Age

From **18 years** old to **60 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant

Sample size

Target sample size: **58**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

It is explained to the patients that they will participate in a clinical trial study and gelfoam administration is not necessary after wisdom tooth surgery according to dental reference books. All surgeries will be performed by the same surgeon using a single protocol and the same type of flap and surgical technique as well as the amount of bone removal. Then, for a series of patients, dexamethasone is used, and for the rest, tranexamic acid with Gelfoam is used, while the patient does not know its type. Then the amount of pain, swelling and bleeding is measured on the first, third and sixth days after surgery.

Placebo

Not used

Assignment

Parallel

Other design features

The number of 58 patients without systemic disease, not taking drugs that interfere with the tested drugs, and also the presence of mandibular wisdom teeth with a moderate degree of severity will be included in the study. Patients were divided into two groups of 29, the first group was administered dexamethasone with Gelfoam and the second group was administered tranexamic acid with Gelfoam. It is explained to the

patients that they should call or refer if there is a specific problem or evidence of infection. Otherwise, the amount of pain, swelling and bleeding is measured on the first, third and sixth days.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Hormozgan University of Medical Sciences

Street address

University of Medical Sciences campus, Shahrak Nabuvat, The beginning of Imam Hossein Blvd

City

Bandar Abbas

Province

Hormozgan

Postal code

7919693116

Approval date

2022-12-24, 1401/10/03

Ethics committee reference number

IR.HUMS.REC.1401.321

Health conditions studied

1

Description of health condition studied

Pain, swelling and bleeding after surgery

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Pain, swelling and bleeding

Timepoint

The first, third and sixth day after surgery

Method of measurement

Clinical examination and using a visual analog scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The use of dexamethasone-impregnated gelfoam in the socket of the mandibular

wisdom tooth
Category
Prevention

2

Description

Intervention group: The use of Tranxamic acid-impregnated gelfoam in the socket of the mandibular wisdom tooth

Category
Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center
Dr. Hossamuddin Etemadi's office
Full name of responsible person
Dr. Hossamuddin Etemadi
Street address
8th floor, Kimia Building, Binesh Alley, 7, Fatemieh Crossroads, in front of Shirinkadeh
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hessam12002@hotmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Bandare-abbas University of Medical Sciences
Full name of responsible person
Dr. Hossamuddin Etemadi
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Bandar Abbas Faculty of Dentistry ,Nasser 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
Bandare-abbas University of Medical Sciences
Proportion provided by this source
50
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
Bandare-abbas University of Medical Sciences
Full name of responsible person
Dr. Hossamuddin Etemadi
Position
Assistant Professor
Latest degree
Specialist
Other areas of specialty/work
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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

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data can be played after de-identifying the participants

When the data will become available and for how long

6 months after recording the results

To whom data/document is available

Academic researchers

Under which criteria data/document could be used

Systematic review articles

From where data/document is obtainable

Email: neda1223roz@gmail.com Its owner: Fatme Zahmtakash

What processes are involved for a request to access data/document

Send email

Comments