

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

The effect of locally applied gelofen in postoperative complication after wisdom tooth surgery

Protocol summary

Study aim

The effect of locally applied gelofen in postoperative complication after wisdom surgery

Design

Clinical trial with control group, double-blind, randomized

Settings and conduct

The study will be carried out at the Ardebil Dental School. This double-blind study is a simple randomized controlled trial in which the evaluator and participants are blinded. The intervention group are treated with gelofen-containing gelfoam placed in empty caries of wisdom teeth, and the control group will receive a treatment with gelofen-free gelfoam. Post-operative complications such as pain, bleeding, dry cavity, and swelling will be examined by a questionnaire and through patient examination on days after the surgery.

Participants/Inclusion and exclusion criteria

Inclusion criteria were the age of 14-65 years, having mandibular impacted wisdom teeth, signature of consent
Exclusion criteria included pregnancy, painkiller use, and drug abuse, systemic disease

Intervention groups

The intervention group is treated with gelofen-containing gelfoam (Apadana tak Co., Iran) in the socket of wisdom teeth. The contents of a 400 mg gelofen tablet (Jaber-ibne Hayan Co., Iran) is discharged by a syringe containing 1 cc of gelofen, then transferred to the gelfoam, and inserted into dental socket. The control group will be treated with gelofen-free gelfoam.

Main outcome variables

Pain, bleeding, trismus, Swelling, dry socket

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20181215041988N1**

Registration date: **2019-07-11, 1398/04/20**

Registration timing: **retrospective**

Last update: **2019-07-11, 1398/04/20**

Update count: **0**

Registration date

2019-07-11, 1398/04/20

Registrant information

Name

Pouyan Sigari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 4454 1504

Email address

p.sigari@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-08, 1398/03/18

Expected recruitment end date

2019-07-09, 1398/04/18

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of locally applied gelofen in postoperative complication after wisdom tooth surgery

Public title

Gelofen in wisdom tooth surgery

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Having an impacted mandibular wisdom tooth Age between 14 and 65 years Signature of consent

Exclusion criteria:

Systemic disease Pregnancy Drug abuse Using anti-analgesic drug

Age

From **14 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **34**

Randomization (investigator's opinion)

Randomized

Randomization description

This study will be performed as a randomized double-blind trial in which the patient and the examiner will be absolutely unaware of the contents of the envelope provided to the surgeon. To this end, a total of 34 apparently similar envelopes will be selected and placed in a 17 surgical card packs together with gelofen, and the other 17 surgical envelopes contain no gelofen. The surgeon chooses randomly one of the envelopes before surgery, and will perform the operation according to the envelope type.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this double-blind study, only the researcher(surgeon) will be informed of the main drug or placebo assigned to each patient. The participants will not be informed of the packet contents of the surgery .The patient does not see a dental packet during surgery and the evaluator is also absent during surgery.Neither the participant nor evaluator not know who is in which group .

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

The Ethics Committee of Ardabil University of Medical Sciences

Street address

Vice President of Research,northern side of Ardabil University of Medical Sciences,University Square,University Street

City

Ardabil

Province

Ardabil

Postal code

۵۶۱۸۹-۸۵۹۹۱

Approval date

2019-05-25, 1398/03/04

Ethics committee reference number

IR.ARUMS.REC.1398.085

Health conditions studied

1

Description of health condition studied

Wisdom surgery

ICD-10 code

Y56.7

ICD-10 code description

Dental drugs, topically applied

Primary outcomes

1

Description

Pain

Timepoint

2,4,6,12,24,48 hours after surgery

Method of measurement

visual analogue scale

Secondary outcomes

1

Description

Bleeding

Timepoint

2 days after surgery

Method of measurement

questionnaire

2

Description

Swelling

Timepoint

2 days after surgery

Method of measurement

Measured by ruler from commissure of lip_ lop of ear and countus of eye _ Angle of mandible

3

Description

Trismus

Timepoint

2 days after surgery

Method of measurement

distance between the upper and lower incisal edges in millimeters.

4**Description**

Dry socket

Timepoint

2 days after surgery

Method of measurement

Examination

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

The intervention group is treated with gelofen-containing gelfoam in the socket of wisdom teeth. The contents of a 400 mg gelofen tablet (Jaber-ibne Hayan Co., Iran) is discharged by a syringe containing 1 cc of gelofen, then transferred to the gelfoam (Apadanatac Co., Iran).

Category

Treatment - Drugs

2**Description**

Control group: The control group is treated with gelofen-free gelfoam (Apadanatak Co., Iran. placebo) in the socket of wisdom teeth.

Category

Placebo

Recruitment centers**1****Recruitment center****Name of recruitment center**

Clinic of Ardabil School of Dentistry

Full name of responsible person

Pouyan Sigari

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

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Shahab bohluli

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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

Ardabil 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**

Ardabil University of Medical Sciences

Full name of responsible person

Pouyan Sigari

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Dentistry

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Ardabil University of Medical Sciences

Full name of responsible person

Pouyan Sigari

Position

Assistant professor

Latest degree

Specialist

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Person responsible for updating data

Contact

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Full name of responsible person

Fahimeh Mirakhorloo

Position

دانشجو

Latest degree

A Level or less

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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

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