Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 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 grug

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 sucket contents of the surgery .The patient does not see a dental sucket 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 comissure 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 sucket
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
Street address
Clinic of ardabil school dentistry, Daneshgah Blv, Janbazan Square
City
Ardabil
Province
Ardabil
Postal code
5618953141
Phone
+98 45 3352 3890
Fax
+98 45 3351 0054
Email
dentistry@arums.ac.ir
Web page address
http://www.arums.ac.ir/dentistry/fa

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ardabil University of Medical Sciences
Full name of responsible person
Shahab bohluli
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
Phone
+98 45 3353 4776
Fax
+98 45 3353 4757
Email
research@arums.ac.ir
Web page address
http://www.arums.ac.ir/vcresearch/fa
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
Street address

Ardabil university of medical sciences,Daneshgah Ave,Janbazan square,Ardabil Town

City
Ardabil

Province
Ardabil

Postal code
5618953141

Phone
+98 21 4454 1504

Fax

Email
P.Sigari@arums.ac.ir

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

Other areas of specialty/work
Dentistry

Street address
Ardabil university of medical sciences,Daneshgah Ave,Janbazan square,Ardabil Town

City
Ardabil

Province
Ardabil

Postal code
5618953141

Phone
+98 21 4454 1504

Fax
+98 45 3351 0054

Email
P.Sigari@arums.ac.ir

Web page address
http://www.arums.ac.ir/dentistry/fa

Person responsible for updating data

Contact

Name of organization / entity
Ardabil University of Medical Sciences

Full name of responsible person
Fahimeh Mirakhorloo

Position
دانشجو

Latest degree
A Level or less

Other areas of specialty/work
Dentistry

Street address
Unit 3، No. 123، Farhangian Town, West of Tehran

City
Tehran

Province
Tehran

Postal code
۱۳۹۷۸۶۴۶۶۴

Phone
+98 21 4454 1504

Email
Fahimeh.mirakhorloo_22@yahoo.con

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