

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

A double-blind split-mouth clinical trial to compare hemostatic effect, the amount of pain, and the incidence of dry socket in a new gelatin sponge (dental geltamp) with commercial geltamp in patients who need mandibular first and second molar extraction

Protocol summary

Study aim

Double-blind split-mouth clinical trial to compare hemostatic effect, the amount of pain and the incidence of dry socket in a new gelatin sponge (dental geltamp) with commercial geltamp after mandibular first and second molar extraction in patients referred to the surgical department of Tabriz faculty of dentistry

Design

Double-blind clinical trial with control, parallel groups, randomized on 26 patients requiring split-mouth extraction of the first mandibular molars referred to the surgery department of Tabriz Dental School

Settings and conduct

In each patient, after tooth extraction, a number of manufactured gels will be randomly placed in the dental cavity for dressing, then a commercial gel gels will be placed in the other dental cavity. The amount of pain will be measured in the first 12 hours after tooth extraction and at 24 and 36 hours after tooth extraction. All patients are evaluated 4 days after the onset of silent dryness.

Participants/Inclusion and exclusion criteria

Need for extraction of two mandibular first molars, age between 20-45 years, no corticosteroids, antibiotics in the last month, no coagulation disorders, no acute or uncontrolled infection at the dental surgery site, no malignancy at the dental surgery site, no site exposure Radiation surgery, no oral contraceptives last month, no smoking, no hypertension, diabetes, thyroid disorders and blood diseases. People taking anticoagulants, not signing the consent form, having a systemic disease, patients whose teeth do not come out normally and need surgery and sectioning,

Intervention groups

In each patient after tooth extraction, a production geltamp will be placed in the extracted tooth cavity (test

group). In the other tooth, a commercial geltamp will be placed in the dental cavity (control group).

Main outcome variables

Hemostatic effect, The amount of pain, The incidence of dry socket

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200919048756N4**

Registration date: **2022-05-02, 1401/02/12**

Registration timing: **prospective**

Last update: **2022-05-02, 1401/02/12**

Update count: **0**

Registration date

2022-05-02, 1401/02/12

Registrant information

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-05-19, 1401/02/29

Expected recruitment end date

2022-07-20, 1401/04/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A double-blind split-mouth clinical trial to compare hemostatic effect, the amount of pain, and the incidence of dry socket in a new gelatin sponge (dental geltamp) with commercial geltamp in patients who need mandibular first and second molar extraction

Public title

Comparison of hemostatic effect, the amount of pain and the incidence of dry socket in a new gelatin sponge (dental geltamp) with commercial geltamp

Purpose

Basic science

Inclusion/Exclusion criteria**Inclusion criteria:**

Need for extraction of two mandibular first molars Age between 20-45 years No corticosteroids and antibiotics using in the last month No coagulation disorders No acute or uncontrolled infection at the dental surgery site No malignancy at the dental surgery site No site exposure Radiation surgery No contraceptives using at last month No smoking No hypertension, diabetes, thyroid disorders and blood diseases

Exclusion criteria:

People taking anticoagulants Not signing the consent form Having a systemic disease Patients whose teeth do not come out normally and need surgery and sectioning

Age

From **20 years** old to **45 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **26**

More than 1 sample in each individual

Number of samples in each individual: **2**

In each patient after tooth extraction, a produced geltamp will be placed in the extracted tooth cavity (test group). In the other tooth, a commercial geltamp will be placed in the tooth cavity

Randomization (investigator's opinion)

Randomized

Randomization description

Commercial geltamp and the produced geltamp are both packaged and sterilized. One geltamp will be labeled as group a and the other geltamp will be labeled as group b. The dental surgeon, who is blind to geltamp type, is required to use one type a and one type b in each

patient. The randomization method will be simple and will be alternate. In this way, if in the first patient the geltamp type a will be placed on the right jaw, in the second patient the geltamp type a will be placed on the left, and so on until the end. And of course on the other side the geltamp b will be placed, which will also be alternate.

Blinding (investigator's opinion)

Double blinded

Blinding description

Commercial geltamp and the produced geltamp are both packaged and sterilized. One geltamp will be labeled as group a and the other geltamp will be labeled as group b. One of the researchers and also a statistician is aware of the grouping of geltamps. Both the patient and the dental surgeon who insert the geltamp into the extracted tooth cavity are blind (whether a and b are commercial or manufactured).

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tabriz University of Medical Sciences

Street address

Golgasht St, Daneshgah Ave, Tabriz University of Medical Sciences, Tabriz, Iran

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East Azarbaijan

Postal code

5166614766

Approval date

2022-04-19, 1401/01/30

Ethics committee reference number

IR.TBZMED.REC.1401.082

Health conditions studied**1****Description of health condition studied**

Extraction of the first and second mandibular teeth

ICD-10 code

M27.3

ICD-10 code description

Alveolitis of jaws

Primary outcomes

1

Description

Blood clotting

Timepoint

The amount of bleeding will be recorded after the anesthesia is gone (within 1-4 hours after tooth extraction) and the amount of uncontrollable bleeding after 4 hours will be considered as active bleeding.

Method of measurement

In the study groups, sterile gas is changed every 15 minutes to completely stop the bleeding. The difference in weight of sterile gas at the beginning and after blood absorption will indicate the amount of blood absorption of each sterile gas. The number of sterile gases consumed and the total weight of sterile blood gases absorbed in each group (test and control) will be compared.

2

Description

The amount of pain

Timepoint

The amount of pain will be measured in the first 12 hours after tooth extraction, as well as in the 24 hour period, 36 hours after tooth extraction.

Method of measurement

And the patient will determine the amount of pain in four time periods from 1 (minimum pain) to 10 (maximum pain) by ticking.

3

Description

The incidence of dry socket

Timepoint

All patients will be examined 4 days later and will be evaluated for the occurrence of dry socket.

Method of measurement

All patients are referred for examination 4 days later and are evaluated for dry socket. Clinical examination of the patient and completion of information forms will be used to collect information.

Secondary outcomes

empty

Intervention groups

1

Description

Test group: One of the two first or second mandibular of patients in which the production geltamp (a sponge made of gelatin without any drug) will be placed. How to use; In each patient, after extracting the tooth, a production geltamp will be placed in the extracted tooth cavity. Duration of use: It will remain in the place for at least 4 days (due to the patient's check on the fourth day

due to the occurrence of dry socket) and after that, it can be discarded or left in the place until complete absorption (10 days).

Category

Prevention

2

Description

Control group: One of the two first or second mandibular of patients in which the commercial geltamp (a sponge made of gelatin without any drug) will be placed. How to use; In each patient, after extracting the tooth, a commercial geltamp will be placed in the extracted tooth cavity. Duration of use: It will remain in the place for at least 4 days (due to the patient's check on the fourth day due to the occurrence of dry socket) and after that, it can be discarded or left in the place until complete absorption (10 days).

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Dentistry, Tabriz University of Medical Sciences

Full name of responsible person

Mohammad Ali Ghavimi

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Sponsors / Funding sources

1

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Full name of responsible person

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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
Tabriz 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

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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
Yes - There is a plan to make this available
Statistical Analysis Plan
Yes - There is a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is 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

No - There is not a plan to make this available

Title and more details about the data/document

It will be published as a Persian and English article.

When the data will become available and for how long

From the time of publication of the articles onwards.

To whom data/document is available

public

Under which criteria data/document could be used

For use in studies with detailed citations.

From where data/document is obtainable

Dr. Solmaz Maleki

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

It can be by sending an email or visiting.

Comments