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

Name

Solmaz Maleki Dizaj

Name of organization / entity

Country

Iran (Islamic Republic of)

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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
Comparition 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 scienece
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 geltumps. 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
City
Tabriz
Province
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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Golgasht St, Daneshgah Ave, Tabriz University of Medical Sciences, Tabriz, Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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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

Contact

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Mohammad Ali Ghavimi

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Dentistry

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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