Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Incidence of the dry socket with and without the use of porous gelfum containing curcumin following extraction of impacted wisdom teeth

Protocol summary

Study aim

Incidence of dry socket with and without use of porous gelfum containing curcumin following extraction of impacted wisdom teeth

Design

The clinical trial has a control group, phase zero, with parallel intervention groups, randomized, without blinding, and random sampling method. 38 patients The patients were randomly selected and in each patient the selection of one side tooth as a control or test will be by simple randomization using coins in the form of taps/lines.

Settings and conduct

Patients with two wisdom teeth embedded in both sides of the mouth referred to the surgical department of the dental school are included in the study. The extraction of both teeth in patients will be performed by a surgeon in the same conditions. One side of the tooth (control tooth) is removed normally and the other side (test) is inserted into the cavity of the antimicrobial porous gelatin jelly after removing the tooth. Finally, 3 days and 7 days later for examination for incidence. They are examined silently and the VAS method is used to assess pain.

Participants/Inclusion and exclusion criteria

Inclusion criteria: 1- Having two wisdom teeth with similar position of mesiangular in the mandible 2- Age 18 to 35 years old 3_Non-addiction to drugs and smoking 4_No systemic and skeletal diseases 4- No non-pregnancy of women Exclusion criteria: 1- No patient to refer to the other side for extraction of teeth on the other side and subsequent evaluations 2- Smoking and drugs after the start of the study and during it 3- Medical treatment 4- Consumption of medicine 5_Sensitivity to study therapies

Intervention groups

Control group: Teeth are extracted normally. Experimental group: Insertion of porous antimicrobial gelatin gelfum after tooth extraction

Main outcome variables

Occurrence of silent drift (pain, unpleasant odor and lack of proper clot formation in the extracted tooth cavity)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20130710013938N5**
Registration date: **2021-08-10, 1400/05/19**
Registration timing: **registered_while_recruiting**

Last update: **2021-08-10, 1400/05/19**
Update count: **0**

Registration date

2021-08-10, 1400/05/19

Registrant information

Name

Mohamadali Ghavimi

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 41 3335 5968

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-02, 1400/04/11

Expected recruitment end date

2021-11-02, 1400/08/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Incidence of the dry socket with and without the use of porous gelfum containing curcumin following extraction of impacted wisdom teeth

Public title

The effect of using a new material (porous gelfum) on the tooth cavity when extracting impacted wisdom teeth

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Having two wisdom teeth with the similar mesioangular position in the mandible No addiction to drugs and smoking Lack of systemic and bone diseases Women are not pregnant Age 18 to 35 years

Exclusion criteria:

Failure to refer the patient for extraction of the other side tooth and subsequent evaluations Smoking and drug use after and during the study Undergoing medical treatment taking medication Sensitivity to study therapies

Age

From **18 years** old to **35 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **38**

More than 1 sample in each individual

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

One side tooth will be considered as a control and the opposite side tooth will be considered as a test.

Randomization (investigator's opinion)

Randomized

Randomization description

Thirty-eight patients who refer to the Department of Surgery of the School of Dentistry for their wisdom tooth surgery agree to carry out this research project and complete informed consent and form our study community. Patients are randomly selected and in each patient, the selection of one side tooth as control or test will be by simple randomization using coins in the form of taps/lines. Each patient who enters the study will be assigned a code from 1 to 38.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committe of Tabriz University of Medical Sciences

Street address

3rd floor, No2 Centeral Building , Tabriz University of Medical Sciences, ,Golgasht street

City

Tabriz

Province

East Azarbaijan

Postal code

5166614711

Approval date

2021-02-22, 1399/12/04

Ethics committee reference number

IR.TBZMED.REC.1399.1097

Health conditions studied

1

Description of health condition studied

Impacted wisdom tooth

ICD-10 code

K01.1

ICD-10 code description

Impacted teeth

Primary outcomes

1

Description

Occurrence of silent drift (pain, unpleasant odor and lack of proper clot formation in the extracted tooth cavity)

Timepoint

3 days and 7 days later

Method of measurement

Patients are given questionnaires that indicate their pain on the first, second, and ... days until the 7th day in the form of numbers from 1 to 10. Clinical examination of the patient and completion of information forms are used to collect information and the Visual Analogue Scale method is used to assess pain.

Secondary outcomes

empty

Intervention groups

1

Description

Control group: All patients were randomly selected and after completing the questionnaire, they were approved by at least two professors of the surgical department. Before the operation, chlorhexidine mouthwash was prescribed and gelofen was administered to them. Extraction of both teeth will be performed by a surgeon under the same conditions. To anesthetize patients, 3 carpol lidocaine containing epinephrine 1 in 80,000 was used and performed with lower alveolar block and long buccal technique. In patients in this group, teeth are extracted normally. To unify the patients, if the time difference between the two operations (from the beginning of the operation to the moment of the last suture) is more than 10 minutes, the patient will be excluded from the study. Silent examination (pain, unpleasant odor and lack of proper clot formation in the extracted tooth cavity) are examined; Patients are given questionnaires that indicate their pain on the first, second and ... days until the 7th day in the form of numbers from 1 to 10. Clinical examination of the patient and completion of information forms are used to collect information and VAS method is used to assess pain.

Category

Treatment - Drugs

2

Description

Intervention group: All patients were randomly selected and after completing the questionnaire, they were approved by at least two professors of the surgical department. Before the operation, chlorhexidine mouthwash was prescribed and gelofen was administered to them. Extraction of both teeth will be performed by a surgeon under the same conditions. To anesthetize patients, 3 carpol lidocaine containing epinephrine 1 in 80,000 was used and performed with lower alveolar block and long buccal technique. After tooth extraction, an antimicrobial porous gelatin gel (containing curcumin nanoparticles) is placed inside the cavity. The prepared gelfomes were cut into 1: 1 by 1 cm dimensions and sterilized by gamma rays. Zelfum has a spongy structure with pores of 200 nm and a loading percentage of 96% curcumin and a slow release pattern of curcumin. To unify the patients, if the time difference between the two operations (from the beginning of the operation to the moment of the last suture) is more than 10 minutes, the patient will be excluded from the study. Silent examination (pain, unpleasant odor and lack of proper clot formation in the extracted tooth cavity) are examined; Patients are given questionnaires that indicate their pain on the first, second and ... days until the 7th day in the form of numbers from 1 to 10. Clinical examination of the patient and completion of information forms are used to collect information and VAS method is used to assess pain.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Tabriz University of Medical Sciences

Full name of responsible person
Mohammadali Ghavimi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Tabriz University of Medical Sciences

Full name of responsible person
Prof. Mohammad Samiei

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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
Private

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
Mohammadali Ghavimi

Position
Associate Professor

Latest degree
Subspecialist

Other areas of specialty/work
Dentistry

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Person responsible for scientific inquiries

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Position
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Latest degree
Subspecialist

Other areas of specialty/work
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Person responsible for updating data

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Position
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Latest degree
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Other areas of specialty/work
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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