

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the antibacterial effect of tetracycline gel and gel containing mesoporous silica nanoparticles loaded with tetracycline in the gingival sulcus fluid at the site of junction between the implant and the abutment

Protocol summary

Study aim

Comparison of the antibacterial effect of tetracycline gel and gel containing mesoporous silica nanoparticles loaded with tetracycline in the gingival groove fluid at the junction of implant and abutment

Design

A trial will include a group with three samples per person, two test implants, and one control implant (without medication).

Settings and conduct

According to the defined entry and exit criteria, 18 patients who need at least 3 mandibular implants are included in the study. In the uncovering session, tetracycline gel and gel containing mesoporous silica nanoparticles loaded with tetracycline are placed in two fixtures and no other substance is applied in the another fixture. Then, in three sessions of prosthesis impression, prosthesis delivery and one month after delivery, a sample of gingival groove fluid is prepared using a paper point and sent to the microbiology laboratory to measure the amount of bacteria present.

Participants/Inclusion and exclusion criteria

1. At least 3 implants in one jaw, minimum age of 18 years, pocket depth of implant 1-3, supra gingival margin, At least 4 months have passed since the extraction of the replacement teeth
2. Breastfeeding, Pregnancy, Patients receiving antibiotics in the last 6 months, systemic disease that affects oral health, Addiction, allergy to tetracycline, People with coronavirus and suspected of it, patients need graft and bone reconstruction, 9- Presence of periodontal disease in other

Intervention groups

There will be two test implants (tetracycline gel and nanoparticle gel containing tetracycline) and one control implant (without any medication)

Main outcome variables

Ability to reduce microbial load and prevent pre-implantitis

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210306050605N1**

Registration date: **2021-04-20, 1400/01/31**

Registration timing: **prospective**

Last update: **2021-04-20, 1400/01/31**

Update count: **0**

Registration date

2021-04-20, 1400/01/31

Registrant information

Name

fahimeh mirzaali

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 41 3335 5921

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-05-22, 1400/03/01

Expected recruitment end date

2021-08-23, 1400/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the antibacterial effect of tetracycline gel and gel containing mesoporous silica nanoparticles loaded with tetracycline in the gingival sulcus fluid at the site of junction between the implant and the abutment

Public title

Comparison of the effect of tetracycline gel and gel containing mesoporous silica nanoparticles loaded with tetracycline on reducing microbial infection at the junction of implant and abutment

Purpose

Basic science

Inclusion/Exclusion criteria**Inclusion criteria:**

1- Having at least 3 implants in one jaw 2- Having a minimum age of 18 years 3- The depth of the probe around the implant is between 1-3 mm (height of the abutment heel inside the gingiva is maximum 3 mm) 4- Possibility of placing zirconia crown with upper gingival margin 5- At least 4 months have passed since the extraction of the replacement teeth.

Exclusion criteria:

1- Pregnant and lactating women 2- Patients receiving antibiotics in the last 6 months 3- Having any systemic disease such as diabetes that affects oral health 4- Addiction to drugs, cigarettes or alcohol 5- History of allergy to tetracycline 6- Based on the flowchart of diagnosis of covid 19 in the levels of outpatient services for definite people with coronary heart disease and suspected of it (1. History of dry cough or chills or sore throat with shortness of breath with or without fever, which can be justified by another etiological factor 2. A patient with fever or respiratory symptoms (whatever the severity): A. Have a history of close contact with a probable / definite case of covid 19 within 14 days prior to the onset of symptoms. Health personnel) 7- Patients with bone thickness less than 5 mm in cbct and patients need graft and bone reconstruction 8- Presence of periodontal disease in other

AgeFrom **18 years** old**Gender**

Both

Phase

N/A

Groups that have been masked*No information***Sample size**Target sample size: **15**

More than 1 sample in each individual

Number of samples in each individual: **3**

People who have 3 implants in the mandible, two of them will be as test implants and one of them will be as control implant (without medication).

Randomization (investigator's opinion)

Not randomized

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**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

City

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East Azarbaijan

Postal code

5166614766

Approval date

2021-02-28, 1399/12/10

Ethics committee reference number

IR.TBZMED.REC.1399.1096

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

periodontitis

ICD-10 code

M27.62

ICD-10 code description

Post-osseointegration biological failure of dental implant

Primary outcomes**1****Description**

The Measurement of the amount of bacteria after placing tetracycline gel and gel containing tetracycline-loaded nanoparticles in the implant for three times

Timepoint

10 days 15 days 30 days after placing the sample

Method of measurement

Bacterial colony counting method

Secondary outcomes

empty

Intervention groups

1

Description

The first intervention group: first implant. Material used in the first intervention group: Tetracycline gel (with a water base containing one percent tetracycline and two percent gel) Frequency, method and duration of use: In the uncovering session, the gel is placed inside the implant with a syringe and the healing abutment is closed. Then, in three sessions: implantation, impression (10 days after the healing abutment closure session), prosthesis delivery (15 days after the impression session) and one month after prosthesis delivery, patients are sampled. Sampling intervals will be the same for all patients. To prepare the gel, carbomer 940 gel (drug grade, product of Bismuth Company) is used.

Category

Treatment - Drugs

2

Description

Intervention group: the second implant. Gel containing tetracycline-loaded mesoporous silica nanoparticles (with a mean particle size of 100 nm and needle morphology) containing tetracycline gel). Frequency, method and duration of use: In the uncovering session, the gel is placed inside the implant with a syringe and the healing abutment is closed. Then, in three sessions: implantation, impression (10 days after the healing abutment closure session), prosthesis delivery (15 days after the impression session) and one month after prosthesis delivery, patients are sampled. Sampling intervals will be the same for all patients. A summary of how mesoporous silica nanoparticles are prepared and how tetracycline is loaded into them is that the mixture of surfactant (CTAB), distilled water and sodium hydroxide (NaOH) is stirred on the stirrer for up to 80 ° C for 30 minutes. The pH of the solution is then adjusted to 12.2. In the next step, tetraethyl orthosilica (Sigma Aldrich brand) is added to the solution immediately under a 550 RPM stirrer. A white precipitate is deposited. The ambient temperature of the solution is maintained at 80 ° for two hours. Tetracycline (a product of Sigma) is dissolved in ethanol. The prepared nanoparticle powder is added to the drug solution. The resulting mixture is gently stirred at room temperature on the stirrer for 48 hours in the dark. The product is mesoporous silica nanoparticles contains tetracycline.

Category

Treatment - Drugs

3

Description

Control group: the third implant. No substance is used.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Private office of Dr. Fereydoon Parnia

Full name of responsible person

Dr. Fereydoon Parnia

Street address

Fourth floor, Jahansar building, Saadi corner, Valiasr Ave, 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
Fereydoon Parnia
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Associate professor
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Person responsible for updating data

Contact

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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

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Not applicable

Title and more details about the data/document

Not applicable

When the data will become available and for how long

From 2021 onwards

To whom data/document is available

There is no limit

Under which criteria data/document could be used

Academic member of Iranian universities

From where data/document is obtainable

Dr. Fahimeh Mirzaali- negarmirzaali1@gmail.com

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

Send documents by email

Comments