Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jun 2026

The comparison of the effect of tetracycline sterile ophthalmic ointment as an adjvant to mechanical debridement and mechanical debridement alone in peri-implantitis treatment

Protocol summary

Study aim

The comparison of the effect of tetracycline sterile ophthalmic ointment as an adjvant to mechanical debridement and mechanical debridement alone in peri-implantitis treatment

Design

A single-blind randomized clinical trial with parallel groups on 32 patients.

Settings and conduct

In this study, 32 patients with pre-implantitis will be treated topically using tetracycline sterile eye ointment. Patients aged 20 years and older with pre-implantitis and radiographic bone resorption.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Presence of pre-implantitis, no history of pre-implant surgery, gingival margin to more than 6 mm deep envelope, positive bleeding, no antibiotics and mouthwash and periodontal treatment in the last 6 weeks, no anti-use Biotics and mouthwash and periodontal treatment are in the last 6 weeks. Exclusion criteria include pregnancy and breast feeding, use of anticoagulants, allergy to tetracycline sterile eye ointment, underlying disease (diabetes, kidney disorders, etc.) and smoking.

Intervention groups

Intervention group: After local anesthesia (Xylocaine Dental (lidocaine HCl)) and isolation and drying of tetracycline ointment (AEROTEX) surfaces by placing a flexible needle (cannula blunt) in the periodontal pouch without trauma or damage to periodontal tissue. (Periodontal cover is not placed.) And then patients will undergo mechanical debridement. Control group: After local anesthesia (Xylocaine Dental (lidocaine HCl)) and isolation and drying, patients will undergo mechanical debridement.

Main outcome variables

Presence or absence of plaque on tooth and implant surfaces (mesial, distal, buccal and lingual surfaces), The distance between the gingival margin and the depth of the envelope is in millimeters, Presence or absence of bleeding after probing, The distance between the acrylic stent and the depth of the pocket.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210909052418N1**
Registration date: **2021-10-31, 1400/08/09**
Registration timing: **prospective**

Last update: **2021-10-31, 1400/08/09**
Update count: **0**

Registration date

2021-10-31, 1400/08/09

Registrant information

Name

mohammad amin mesforoush

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3237 3382

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-06, 1400/08/15

Expected recruitment end date

2022-01-05, 1400/10/15

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The comparison of the effect of tetracycline sterile ophthalmic ointment as an adjvant to mechanical debridement and mechanical debridement alone in peri-implantitis treatment

Public title
The comparison of the effect of tetracycline sterile ophthalmic ointment as an adjvant in peri-implantitis treatment
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Presence of pre-implant disease No history of pre-implant surgery treatment PD>6 mm Positive BOP BOL<2mm No use of antibiotics and mouthwash and periodontal treatment in the last 6 weeks. No use of antibiotics and mouthwash and periodontal treatment in the last 6 weeks
Exclusion criteria:
Pregnancy and breast feeding Using anticoagulants Allergy to tetracycline sterile eye ointment Underlying disease (diabetes, kidney disorders, etc.) Smoking
Age
From **20 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **32**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization will be using sealed envelopes, of which 32 envelopes will be selected in total and will be divided into two categories of 16, which include groups A and B. At the beginning of the patients' arrival, the secretary of the clinic randomly provides the envelopes to the patients and the patients select them and enter the examination area with the envelopes, and then the dentist will determine the group of patients using the envelopes.
Blinding (investigator's opinion)
Single blinded
Blinding description
The person evaluates the outcome of patients compared to blind study groups. Patients will be treated by the first and second study supervisors.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Vice chancellor for research, Tabriz University of Medical Sciences
Street address
Vice chancellor for research, Tabriz University of Medical Sceinces, Daneshgah Square
City
Tabriz
Province
East Azarbaijan
Postal code
5166614766
Approval date
2021-08-30, 1400/06/08
Ethics committee reference number
IR.TBZMED.REC.1400.516

Health conditions studied

1

Description of health condition studied
peri-implantitis
ICD-10 code
M27.69
ICD-10 code description
Other endosseous dental implant failure

Primary outcomes

1

Description
Presence or absence of plaque on tooth and implant surfaces (mesial, distal, buccal and lingual surfaces)
Timepoint
1 and 3 months after the intervention
Method of measurement
Clinical dental examination

2

Description
The distance between the gingival margin and the depth of the envelope is in millimeters
Timepoint
1 and 3 months after the intervention
Method of measurement
Clinical dental examination

3

Description
Presence or absence of bleeding after probing
Timepoint
1 and 3 months after the intervention
Method of measurement
Clinical dental examination

4

Description
The distance between the acrylic stent and the depth of the pocket
Timepoint
1 and 3 months after the intervention
Method of measurement
Clinical dental examination

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: After local anesthesia (Xylocaine Dental (lidocaine HCl)) and isolation and drying of tetracycline ointment (AEROTEX) surfaces by placing a flexible needle (cannula blunt) in the periodontal pouch without trauma or damage to periodontal tissue. (Periodontal cover is not placed.) And then patients will undergo mechanical debridement.
Category
Treatment - Drugs

2

Description
Control group: After local anesthesia (Xylocaine Dental (lidocaine HCl)) and isolation and drying, patients will undergo mechanical debridement.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Faculty of dentistry
Full name of responsible person
Mohammad-Taghi Chitsazi
Street address
Third Floor, Number 2 central building, Golgasht street
City
Tabriz
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East Azarbaijan
Postal code
5138665793
Phone
+98 41 3335 7310
Email
mtchitsazi@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Mohammad Samiee
Street address
Third Floor, Number 2 central building, Golgasht street
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5138665793
Phone
+98 41 3335 7310
Email
samiei.moh@gmail.com
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 amin Mesforoush
Position
Dentistry student
Latest degree
A Level or less
Other areas of specialty/work
Dentistry
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is 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
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
Study data is categorized and coded with no identifiable individuals.

When the data will become available and for how long
Access to study data after publication of the result is available in the journal.

To whom data/document is available
Anyone interested in using the data can access the study data.

Under which criteria data/document could be used
Study data can be used for comparison with other results.

From where data/document is obtainable
Refer to the study's scientific or public accountability person for data.

What processes are involved for a request to access data/document
The request will be sent by email to person responsible for scientific or public inquiries.

Comments