# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

18 Sep 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**

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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
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## 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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**Postal code**
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**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
**Street address**

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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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**