

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

28 May 2026

### Comparison the microbiological effects of sustain released microspherical minocycline and emdogain in the non-surgical treatment of peri-implant mucosal inflammation

#### Protocol summary

##### Summary

(1) Objectives: To evaluate the effects of micro spherical minocycline and emdogain on the microbial profile of peri-implant inflammatory diseases. (2) Design: Non-superiority of the proposed treatment protocol with a double-blind, two-armed parallel-group design. (3) Population: The patients who recalled for follow-up visits during September 2013 to March 2014 at Periodontics Department of faculty of Dentistry and private practice offices in Tabriz- Iran. (4) Major inclusion criteria for evaluation: Adult patients with at least one implant in function for more than one year and with mild peri-implantitis, defined as: Presence of bleeding on probing, radio-graphic bone loss less than 2mm and the probing depth more than 4mm in at least one site of the peri-implant. (5) Intervention: 20 patients will be recruited for each arm of this trial. Baseline sampling will be recorded and patients randomly will be assigned to receive one of the following treatment protocols: In the first group, mechanical debridement using ultrasonic scaler and air-powder polishing device will be done. In the second group, following mechanical debridement 1 mg of minocycline hydrochloride microspheres will be located subgingivally into the affected sites. In the third group, following mechanical debridement 1 mg of emdogain will be located subgingivally into the affected sites. Numbers of the porphyromonas gingivalis bacteria in gingival crevicular fluid (GCF) will be assessed at baseline, 2 weeks and 3 months after treatments. (6) Main outcome: Changes in numbers of the porphyromonas gingivalis bacteria.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201311103690N4**

Registration date: **2014-01-20, 1392/10/30**

Registration timing: **registered\_while\_recruiting**

Last update:

Update count: **0**

##### Registration date

2014-01-20, 1392/10/30

##### Registrant information

###### Name

Masoomeh Faramarzie

###### Name of organization / entity

Tabriz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 1385 4863

###### Email address

faramarzim@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

##### Expected recruitment start date

2013-08-27, 1392/06/05

##### Expected recruitment end date

2014-03-07, 1392/12/16

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison the microbiological effects of sustain

released microspherical minocycline and emdogain in the non-surgical treatment of peri-implant mucosal inflammation

#### Public title

Effects of minocycline and emdogain in the treatment of peri-implant mucosal inflammation

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria: - Adults aged 18 years and older - Patients with peri-implant inflammation, defined as: Presence of bleeding on probing, probing depth more than 4mm, lack of soft tissue recession, radio-graphic bone loss less than 2mm. - Implant functioning for at least one year Exclusion criteria: - Taking systemic or local antibiotics in the past 3 months - Regular intake of anti-inflammatory drugs in the past 3 months - Any intervention for treatment of peri-implant inflammation in the past 3 months - Poor oral hygiene - Smoking - Long term treatment with any medication that affects soft and hard tissue conditions (such as phenytoin, cyclosporin, calcium canal blockers...) - Pregnancy and lactation - Sever periodontal disease - Uncontrolled diabetes or debilitating systemic disease - Drug and alcohol addiction - Allergy to tetracycline-class drug(s)

#### Age

From **18 years** old to **55 years** old

#### Gender

Both

#### Phase

2

#### Groups that have been masked

*No information*

#### Sample size

Target sample size: **20**

#### Randomization (investigator's opinion)

Randomized

#### Randomization description

#### Blinding (investigator's opinion)

Double blinded

#### Blinding description

#### Placebo

Not used

#### Assignment

Parallel

#### Other design features

Patients will be randomly assigned to receive one of treatment protocols. The allocation sequence will be concealed from the examiner, patients and statistical analyzers. Staff members who obtain the results will not be aware how the study groups are assigned. Moreover the intervention staff, who delivered the intervention will not also be given the results. Therefore, the final results will not be revealed to any of the investigators, staff, or participants.

#### Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Tabriz University of Medical Sciences

##### Street address

Tabriz University of Medical Sciences, Golgasht Ave, Tabriz, Iran

##### City

Tabriz

##### Postal code

5166614713

##### Approval date

2013-10-23, 1392/08/01

##### Ethics committee reference number

92111

## Health conditions studied

### 1

#### Description of health condition studied

mucosal inflammation around dental implants

#### ICD-10 code

A41.5, A41

#### ICD-10 code description

Sepsis due to anaerobes, Sepsis due to other Gram-negative organisms

## Primary outcomes

### 1

#### Description

Numbers of the porphyromonas gingivalis bacteria

#### Timepoint

Before intervention, 2 weeks and 3 months after intervention

#### Method of measurement

The number of bacteria with polymerase chain reaction (PCR)

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Control: Instruction of oral hygiene and debridement of subgingival environment using ultrasonic scaler and glycine-based powder air polishing.

#### Category

Treatment - Drugs

## 2

### Description

Intervention 1 : Two weeks after mechanical debridement, one mg of minocycline hydrochloride microspheres (Arestin OraPharma, Inc USA) will be located subgingivally in the affected sites around the implant.

### Category

Treatment - Drugs

## 3

### Description

Intervention 2 : Two weeks after mechanical debridement, 0.1 ml of Enamel Matrix Derivative Gel (Emdogain) 0.3 ml straumann will be located subgingivally in the affected sites around the implant with the help of syringe.

### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Faculty of Dentistry and private practice offices in Tabriz- Iran

##### Full name of responsible person

Zahra Goharfar

##### Street address

Faculty of Dentistry, Tabriz University of Medical Sciences, Golgasht Ave, Tabriz, Iran

##### City

Tabriz

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for research, Tabriz University of Medical Sciences

##### Full name of responsible person

Mohammad Reza Rashidi

##### Street address

Vice chancellor for research, Tabriz University of Medical Sciences, Golgasht Ave, Tabriz, Iran

##### City

Tabriz

##### Grant name

##### Grant code / Reference number

##### Is the source of funding the same sponsor organization/entity?

Yes

##### Title of funding source

Vice chancellor for research, Tabriz University of Medical Sciences

##### Proportion provided by this source

100

##### Public or private sector

empty

##### Domestic or foreign origin

empty

##### Category of foreign source of funding

empty

##### Country of origin

##### Type of organization providing the funding

empty

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Tabriz University of Medical Sciences, Faculty of Dentistry

#### Full name of responsible person

Zahra Goharfar

#### Position

Resident of Periodontics

#### Other areas of specialty/work

#### Street address

Faculty of Dentistry, Tabriz University of Medical Sciences, Golgasht Ave, Tabriz, Iran

#### City

Tabriz

#### Postal code

5166614713

#### Phone

+98 41 1335 5965

#### Fax

+98 41 1334 6977

#### Email

zgoharfar61@gmail.com

#### Web page address

www.tbzmed.ac.ir

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Faculty of Dentistry, Tabriz University of Medical Sciences

#### Full name of responsible person

Masoomeh Faramarzie

#### Position

Periodontist

#### Other areas of specialty/work

#### Street address

Faculty of Dentistry, Tabriz University of Medical Sciences, Golgasht Ave, Tabriz, Iran

#### City

Tabriz

#### Postal code

5166614713

#### Phone

+98 41 1335 5965

#### Fax

+98 41 1334 6977

#### Email

faramarzim@tbzmed.ac.ir

**Web page address**

www.tbzmed.ac.ir

**Person responsible for updating data**

**Contact**

**Name of organization / entity**

Tabriz University of Medical Sciences, Faculty of Dentistry

**Full name of responsible person**

Zahra Goharfar

**Position**

Resident of Periodontics

**Other areas of specialty/work**

**Street address**

Faculty of Dentistry, Tabriz University of Medical Sciences, Golgasht Ave, Tabriz, Iran

**City**

Tabriz

**Postal code**

5166614713

**Phone**

+98 41 1335 5965

**Fax**

+98 41 1334 6977

**Email**

zgoharfar61@gmail.com

**Web page address**

www.tbzmed.ac.ir

**Sharing plan**

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*