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

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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
mocusal 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
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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
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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
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Resident of Periodontics
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Person responsible for scientific inquiries

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Other areas of specialty/work

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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