

Clinical Trial Protocol

Iranian Registry of Clinical Trials

19 Sep 2026

Sustained release of micro- spherical minocycline for management of peri-implant mucosal inflammation

Protocol summary

Summary

1) Objectives: To evaluate the effects of micro- spherical minocycline on the clinical and cytokine profile of peri-implant inflammatory diseases. (2) Design: Evaluation of non- superiority of the proposed treatment protocol with a double-blind, two-arm parallel-group design. (3) Setting and conduct: The patients who will be recalled to follow-up visits during March - September 2014 at Periodontics Department of Faculty of Dentistry and private practice offices in Tabriz- Iran. (4) Participants' including major eligibility criteria : Adult patients with at least one implant in function for more than one year with peri-implant inflammatory diseases defined as: Presence of Bleeding on probing, with radio-graphic bone loss less than 2 mm and probing depth equal or more than 4 mm in at least one site. (5) Intervention: 25 patients will be recruited for each arm of this trial. Baseline sampling and clinical measurements will be recorded and randomly assigned to receive one of the following treatment protocols: Mechanical debridement using ultrasonic scaler and air-powder polishing device. Mechanical debridement along with one mg of minocycline hydrochloride microspheres will be inserted subgingivally into the affected sites. Clinical data including probing depth (PD), bleeding on probing (BOP), interleukin 6 and 17 in gingival crevicular fluid (GCF) will be assessed at baseline, 2 weeks and 3-months after treatments. (6) Main outcome measures: The primary outcome considered as BOP changes and secondary outcomes will be PD and IL-6, 17 level changes in GCF.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013100114847N1**

Registration date: **2014-01-25, 1392/11/05**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-01-25, 1392/11/05

Registrant information

Name

Zaker Yari Hajatalou

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1335 5965

Email address

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for research of Tabriz University of Medical Sciences

Expected recruitment start date

2014-03-27, 1393/01/07

Expected recruitment end date

2014-08-23, 1393/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Sustained release of micro- spherical minocycline for management of peri-implant mucosal inflammation

Public title

Local antibiotic therapy in peri- implant inflammation

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 1) Adults aged 18 or over with at least one implant in function for more than one year 2) Mild peri-implant inflammatory diseases. defined as: presence of Bleeding on Probing, radio-graphic bone loss at the site of the implant less than 2 mm and probing depth more than 4 mm Exclusion criteria: 1) Any related systemic diseases 2) Smoking 3) Pregnancy and lactation 4) Active periodontal disease 5) Consumption of systemic antibiotics in the late 3 months 6) Need for bacterial prophylaxis with systemic antibiotics 7) Long-term use of any drug affects periodontal tissue conditions 8) Probing depth greater than 6 mm at base line visit 9) Drug and alcohol abuse 10) Uncontrolled diabetes 11) Probing depth less than 4 mm at base line visit

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double 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

Department of periodontics, School of Dentistry, Tabriz University of Medical Sciences, Golgasht Street

City

Tabriz

Postal code

Approval date

2013-08-01, 1392/05/10

Ethics committee reference number

9268

Health conditions studied

1

Description of health condition studied

Periimplantitis

ICD-10 code

T85.8

ICD-10 code description

Other complications of internal prosthetic devices, implants and grafts, not elsewhere classified

Primary outcomes

1

Description

Bleeding on probing (BOP)

Timepoint

Baseline, 2 week and 3 month later

Method of measurement

Periodontal Probe

Secondary outcomes

1

Description

Peri implant probing depth

Timepoint

Baseline, after 2 weeks, after 3 month

Method of measurement

Periodontal prob

2

Description

cytokines level in gingival crevicular fluid (GCF): IL-6, IL-17

Timepoint

Baseline, 2 week and 3 month later

Method of measurement

ELISA test

Intervention groups

1

Description

Control group: Mechanical debridement using ultrasonic scaler and air-powder air polishing device.

Category

Treatment - Devices

2

Description

Intervention: Two weeks after mechanical debridement, a one mg of minocycline hydrochloride microspheres introduced subgingivally into the affected sites.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of Dentistry, Tabriz University of Medical Sciences

Full name of responsible person

Reza Pourabbas (Periodontist, Professor)

Street address

Department of periodontics, School of Dentistry,
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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Reza Pourabbas

Position

Periodontics/ Professor

Other areas of specialty/work

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for research of Tabriz University of
Medical Sciences

Full name of responsible person

Reza Pourabbas (Professor)

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Department of periodontics, School of Dentistry,
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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 of 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

Full name of responsible person

Reza Pourabbas

Position

Periodontics/ Professor

Other areas of specialty/work

Street address

Person responsible for updating data

Contact

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Zaker Yari Hajatalou

Position

DDS/ periodontics resident

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