

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Effect of adjunctive locally delivered doxycycline microspheres on clinical parameters and the gingival crevicular fluid matrix metalloproteinase-8 levels in chronic periodontitis

Protocol summary

Summary

The aim of current investigation was to study effect of periodontal non-surgical treatment along with locally delivered doxycycline microspheres on clinical parameters and the gingival crevicular fluid matrix metalloproteinase -8 level in patients with chronic periodontitis. Present single-blind study was carried out on patients referred to faculty of dentistry of Tabriz, having moderate to severe chronic periodontitis, at least four teeth with probe depth of 4-6 mm where 2 teeth were in one Quadrants and two other teeth were at the opposite Quadrants. The patients had no sensitivity to tetracycline antibiotics, no periodontal treatment for recent 6 months, no systematic difficulty. The patient was excluded from the study if he had SRP, periodontal treatment till 6 months before, every systematic disorder and allergy history to tetracycline antibiotics. 25 patients with moderate to severe chronic periodontitis were selected. The research method was split mouth. Two teeth were selected as test group and the two adjacent teeth were also selected as control group. No Baseline sampling intervention was considered in the groups to determine mmp8 level of Gingival Crevicular fluid and evaluate clinical parameters. So, the treatment was non-surgical periodontal in the both groups and, instantly, locally delivered doxycycline was placed in the pockets in the test group. Sampling and clinical parameters evaluation was carried out again 1 and 3 months later. One month is needed for taking the patient and four months for treatment. initial result was evaluation of changes in mmp8 level of Gingival Crevicular fluid.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201601173690N6**

Registration date: **2016-03-13, 1394/12/23**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-03-13, 1394/12/23

Registrant information

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Recruitment status

Recruitment complete

Funding source

Gingival and dental research center of Tabriz dentistry faculty

Expected recruitment start date

2016-02-18, 1394/11/29

Expected recruitment end date

2016-05-26, 1395/03/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of adjunctive locally delivered doxycycline

microspheres on clinical parameters and the gingival crevicular fluid matrix metalloproteinase-8 levels in chronic periodontitis		Street address	Faculty of dentistry , Tabriz university of medical sciences tabriz
Public title		City	TABRIZ
Effect of adjunctive locally delivered doxycycline microspheres on clinical parameters and the gingival crevicular fluid matrix metalloproteinase-8 levels in chronic periodontitis		Postal code	
Purpose		Approval date	2016-01-04, 1394/10/14
Treatment		Ethics committee reference number	TBZMED.REC.1394.918
Inclusion/Exclusion criteria		Health conditions studied	
Inclusion criteria: Patients with moderate to severe chronic periodontitis with at least 4 teeth and 4-6mm probe depth were included in the study whose two teeth were at one quadrant and the other two teeth at opposite quadrant of the same patient. The patients shouldn't have sensitivity to antibiotics of tetracycline group and they also, should not have periodontal treatment till 6 months before. Moreover they shouldn't take antibiotics 3 months before treatment. Finally they shouldn't have systemic problem which affects periodontal tissues. If the patient had one of following cases, he would be excluded from the study: Having SRP and every periodontal treatment till 6 months before the study, presence of every systemic disorder affecting periodontal position, having allergy history to doxycycline or antibiotics of tetracycline group and taking antibiotics 3 months before the study.		1	
Age		Description of health condition studied	
No age limit		Chronic periodontitis	
Gender		ICD-10 code	
Both		K05.3	
Phase		ICD-10 code description	
N/A		Chronic periodontitis	
Groups that have been masked		Primary outcomes	
No information		1	
Sample size		Description	
Target sample size: 25		gingival crevicular fluid matrix metalloproteinase-8 levels	
Randomization (investigator's opinion)		Timepoint	
Randomized		Baseline , 1 and 3 months after treatment	
Randomization description		Method of measurement	
Blinding (investigator's opinion)		Ng/ml ,ELISA using Quantikine human total MMP-8 immunoassay kits	
Single blinded		Secondary outcomes	
Blinding description		1	
Placebo		Description	
Not used		Evaluation of prob depth , attachment level and bleeding of probing	
Assignment		Timepoint	
Parallel		Baseline, 1and 3 months after treatment	
Other design features		Method of measurement	
		By prob , pocket depth and attachment level :mm	
Secondary Ids		Intervention groups	
empty		1	
Ethics committees		Description	
1		Test group: Initial sampling was carried out before every intervention to determine mmp8 level of gingival crevicular fluid and evaluate clinical parameters including probe depth, attachment level and bleeding of probing. Hence,the treatment was periodontal non surgical(i.e.Scailing and Root planing) 10% local doxycycline was placed , instantly, inside the pocket in the test group.1-3months later the sampling and evaluation of clinical parameters were repeated.	
Ethics committee		Category	
Name of ethics committee			
University of Tabriz medical science			

Treatment - Drugs

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Description

Control group Initial sampling was carried out before every intervention to determine mmp8 amount of Gingival Crevicular fluid and evaluate clinical parameters including probe depth, Attachment level and bleeding of probing. Hence, the treatment was periodontal non-surgical (i.e. Scaling and Root planing). 1-3 months later the sampling and evaluation of clinical parameters were repeated.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Faculty of dentistry , Tabriz university of medical science

Full name of responsible person

Dr faramarzi

Street address

Faculty of dentistry , Tabriz university of medical science

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gingival and dental research center of Tabriz dentistry faculty

Full name of responsible person

Dr shahi

Street address

Faculty of dentistry ,

City

Tabriz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Gingival and dental research center of Tabriz dentistry faculty

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

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Full name of responsible person

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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