Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparative Evaluation of Mucoadhesive Locally Delivery Tetracycline Gel and Tetracycline Gel in Treatment of Chronic Periodontitis

Protocol summary

Summary

The purpose of this study is to compare the effectiveness of muco-adhesive Tetracycline gel with that of the common Tetracycline gel as an adjunctive topical treatment medicine following scaling and root planning (SRP), and to compare them with the outcomes of treating chronic periodontitis by performing SRP only. This is a randomized, triple-blind, placebo controlled study. Samples are chosen from patients suffering from chronic periodontitis who referred to Kermanshah Faculty of Dentistry. The major inclusion criteria consists of: No present systemic disease; At least 3 areas with probing depth of 5 mm at least; No history of allergy to Tetracycline; No history of antibiotic therapy, prophylaxis, or periodontal treatment during the last 6 months. Exclusion criteria: Pregnant and nursing patients. The study is conducted on 75 areas of at least 5 mm of pocket depth. In each patient after scaling and root planing, muco-adhesive tetracycline gel is injected in one site, Tetracycline is injected in another site and on the third site placebo is injected. Actually, therapy is divided into 3 groups so that 25 sites will receive SRP and placebo; in another 25 sites, muco-adhesive Tetracycline is injected into the pockets immediately after SRP; and in the last 25 sites, Tetracycline is injected into the pockets immediately following SRP. Clinical parameters to be considered including plaque index, gingival index, pocket depth, clinical attachment loss, and bleeding index are evaluated pre-treatment and in 15, 30, and 90 days post-treatment.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016030226872N1**
Registration date: **2016-06-29, 1395/04/09**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2016-06-29, 1395/04/09

Registrant information

Name
maryam khosravi
Name of organization / entity
Kermanshah University of Medical Sciences Dental School
Country
Iran (Islamic Republic of)
Phone
+98 83 3838 9950
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m.khosravi@kums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Kermanshah University of Medical Sciences

Expected recruitment start date

2016-05-21, 1395/03/01

Expected recruitment end date

2016-10-21, 1395/07/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative Evaluation of Mucoadhesive Locally Delivery Tetracycline Gel and Tetracycline Gel in Treatment of Chronic Periodontitis

Public title

Effect of Tetracycline in the treatment of chronic

periodontitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: patient free from systemic illness; patients who had note history of allergy to tetracycline; patiens having at least three sites with minimum 5 mm periodontal pocket; patient who had not taken antibiotic therapy and prophylaxy and periodontal therapy in the past 6 month Exlusion criteria: dissatisfaction and inability to comply with the follow-up visit requirments; history of systemic illness; received antibiotic treatment 2 weeks prior to study; pregnant and nursing patients

Age

From **30 years** old to **60 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **75**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Patients are recruited from people refer to periodontics department of Kermanshah University Of Medical Science. Each patient will receive different treatment modalities in each quadrant. Randomization was done by toss of coin for quadrants and treatment modalities.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Kermanshah University of Medical Sciences

Street address

Kermanshah University of Medical Sciences, Shahid Beheshti blvd, Kermanshah

City

Kermanshah

Postal code

Approval date

2016-01-20, 1394/10/30

Ethics committee reference number

kums.rec.1394.288

Health conditions studied

1

Description of health condition studied

Chronic periodontitis

ICD-10 code

K05.3

ICD-10 code description

Chronic periodontitis

Primary outcomes

1

Description

probing pocket depth

Timepoint

Baseline, two weeks, one and three months after the intervention

Method of measurement

Williams Periodontal Probe

2

Description

Clinical attachment loss

Timepoint

Baseline, two weeks, one and three months after the intervention

Method of measurement

Williams Periodontal Probe

3

Description

plaque index

Timepoint

Baseline, two weeks, one and three months after the intervention

Method of measurement

plaque index Silness & Loe

4

Description

Gingival Index

Timepoint

Baseline, two weeks, one and three months after the intervention

Method of measurement

Observed

5

Description

Bleeding Index

Timepoint

Baseline, two weeks, one and three months after the intervention

Method of measurement

Observed\Bleeding Index Muhlemann

Secondary outcomes

empty

Intervention groups

1

Description
Control group:SRP with placebo
Category
Placebo

2

Description
Intervention group:SRP with Mucoadhesive Locally Delivery Tetracycline 5%
Category
Treatment - Drugs

3

Description
Intervention group:SRP with Tetracyclin 5%
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Department of Periodontology, Kermanshah faculty of dentistry
Full name of responsible person
Dr Maryam Khosravi
Street address
Opposite post office, Shora st, Dr Shariati st, Kermanshah
City
Kermanshah

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ethics committee of Kermanshah University of Medical Sciences
Full name of responsible person
Kurosh Hamzehee
Street address
Ethics Committe of Kermanshah University of Medical Sceinces, Shahidbeheshti Blvd, Kermanshah
City
Kermanshah
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ethics committee of Kermanshah 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
Kermanshah Dentistry School
Full name of responsible person
Marzie Jamali
Position
Dental student
Other areas of specialty/work
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Person responsible for updating data

Contact

Name of organization / entity
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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