

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

18 Sep 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

###### Email address

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

#### Street address

Opposite of the post office, Shora st, Dr Shariati st,  
Kermanshah

#### City

kermanshah

#### Postal code

#### Phone

+98 83 3722 2400

#### Fax

#### Email

m.jamali174@gmail.com

#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Kermanshah Dentistry School

#### Full name of responsible person

Dr Maryam Khosravi

#### Position

Phd

#### Other areas of specialty/work

#### Street address

Opposite of the post office, Shora st, Dr Shariati st,  
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#### Phone

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#### Fax

#### Email

m.khosravi@kums.ac.ir

**Web page address**

## **Person responsible for updating data**

### **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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m.jamali174@gmail.com

**Web page address**

## **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*