

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Evaluation effect of mucoadhesive nigella sativa in the treatment of chronic periodontitis

#### Protocol summary

##### Summary

The purpose of this study is to compare the effectiveness of muco-adhesive Nigella Sativa extract with muco-adhesive Thymoquinone 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. Inclusion criteria: patient free from systemic illness; patient who had not taken periodontal therapy in the past 3 month Exclusion criteria: dissatisfaction and inability to comply with the follow-up visit requirements; history of systemic illness; received antioxidants like vitamin C and E or  $\beta$ -Carotene; pregnant. In each patient after scaling and root planing, muco-adhesive Nigella Sativa gel is injected in one site, muco-adhesive Thymoquinone gel is injected in another site and on the third site placebo is injected. Clinical parameters to be considered including plaque index, gingival index, pocket depth, clinical attachment loss, and bleeding index are evaluated pre-treatment and in 8, 15, 30, and 90 days post-treatment.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016021826637N1**

Registration date: **2017-02-15, 1395/11/27**

Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-02-15, 1395/11/27

#### Registrant information

##### Name

Seyed Mohamad Saleh Yassini

##### Name of organization / entity

Kermanshah University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 83 3845 2545

##### Email address

sms.yassini@kums.ac.ir

#### Recruitment status

##### Recruitment complete

#### Funding source

Vice chancellor for research, Kermanshah University of Medical Sciences

#### Expected recruitment start date

2016-07-22, 1395/05/01

#### Expected recruitment end date

2016-08-10, 1395/05/20

#### Actual recruitment start date

empty

#### Actual recruitment end date

empty

#### Trial completion date

empty

#### Scientific title

Evaluation effect of mucoadhesive nigella sativa in the treatment of chronic periodontitis

#### Public title

Effect of nigella sativa in the treatment of chronic periodontitis

#### Purpose

Treatment

#### Inclusion/Exclusion criteria

Inclusion criteria: patient free from systemic illness; patient who had not taken periodontal therapy in the past 3 month Exclusion criteria: dissatisfaction and

inability to comply with the follow-up visit requirements; history of systemic illness; received antioxidants like vitamin C and E or  $\beta$ -Carotene; pregnant

#### Age

No age limit

#### 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)

Triple blinded

#### Blinding description

#### Placebo

Used

#### Assignment

Parallel

#### Other design features

### 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

2016-06-08, 1395/03/19

##### Ethics committee reference number

KUMS.REC.1395.176

### 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, one week, two weeks, one and three months after the intervention

##### Method of measurement

Williams Periodontal Probe

#### 2

##### Description

Clinical attachment loss

##### Timepoint

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

##### Method of measurement

Williams Periodontal Probe

#### 3

##### Description

plaque index

##### Timepoint

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

##### Method of measurement

plaque index Silness & Loe

#### 4

##### Description

Gingival Index

##### Timepoint

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

##### Method of measurement

Observed

#### 5

##### Description

Bleeding Index

##### Timepoint

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

##### Method of measurement

Observed\Bleeding Index Muhlemann

### Secondary outcomes

empty

### Intervention groups

#### 1

##### Description

Intervention group:SRP with Mucoadhesive Locally Delivery Nigella Sativa extract 0.2%

##### Category

Treatment - Drugs

## 2

### Description

Intervention group:SRP with Mucoadhesive Locally  
Delivery Thymoquinone 0.02%

### Category

Treatment - Drugs

## 3

### Description

Control group:SRP with placebo

### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Department of Periodontology, Kermanshah faculty of  
dentistry

##### Full name of responsible person

##### Street address

##### 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

Seyed Mohamad Saleh Yassini

#### Position

Dental student

#### Other areas of specialty/work

#### Street address

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

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#### Phone

+98 83 3722 2400

#### Fax

#### Email

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#### Web page address

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Kermanshah Dentistry School

#### Full name of responsible person

Dr Narges Ziaei

#### Position

Phd

#### Other areas of specialty/work

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## Person responsible for updating data

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#### Other areas of specialty/work

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**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*