Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 Exlusion criteria: dissatisfaction and inability to comply with the follow-up visit requirments; history of systemic illness; received antioxidants like vitamin C and E or β-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

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Name of organization / entity
Kermanshah University of Medical Sciences
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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 Exlusion criteria: dissatisfaction and

inability to comply with the follow-up visit requirments; history of systemic illness; received antioxidants like vitamin C and E or β-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
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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
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Person responsible for updating data

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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