Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Preparation an oral gel-made from thymoquinone (TQ), and clinical study investigating the efficacy of it on patients with aphtha

Protocol summary

Summary

Objective: The therapeutic effect of Nigella sativa Linn extract has been widely proved of ancient to now. It is suggested that an herbal product from Nigella sativa extract in the form of a gel may be beneficial in treatment of RAS. The aim of this study is to evaluate the efficacy of a gel prepared from Nigella sativa Linn extract on the clinical management of RAS patients. Design: The present study is a randomized, double-blind, and placebo-controlled study that is conducted on 56 patients diagnosed to have aphtatous ulcers. Setting and conduct: 28 patients were advised to apply thymoquinone gel twice times a day for one month and the other 28 patients were given placebo gel for the same duration. Efficacy evaluations are made on the four times during one-month period. Patient exclusion criteria: These include: Drug usage or any treatment occurring before dental treatment; systemic diseases; hypersensitivity history; smoking habits or alcoholism; pregnancy and lactation; orthodontic instruments. Primary outcome measure are duration of healing, size of lesion, pain in lesion and erythema. Data were analyzed using the repeated measures ANOVA, paired and independent t-test.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016100914106N5**
Registration date: **2017-09-12, 1396/06/21**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-09-12, 1396/06/21

Registrant information

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Reza Tahvilian
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 Science

Expected recruitment start date

2017-08-21, 1396/05/30

Expected recruitment end date

2017-12-21, 1396/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Preparation an oral gel-made from thymoquinone (TQ), and clinical study investigating the efficacy of it on patients with aphtha

Public title

Preparation an oral gel-made from thymoquinone (TQ), and clinical study investigating the efficacy of it on patients with aphtha

Purpose

Treatment

Inclusion/Exclusion criteria

Patient inclusion criteria include: possessing aphtatous

ulcer; patients without systemic diseases, hypersensitivity history; smoking habits or alcoholism; pregnancy and lactation; orthodontic instruments. Patient exclusion criteria include: Drug usage or any treatment occurring before dental treatment.

Age
No age limit

Gender
Both

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **56**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Kermanshah University of Medical Science

Street address
Central building, Beheshti Blvd, Kermanshah University of Medical Science update Kermanshah

City
Kermanshah

Postal code
6715847141

Approval date
2017-07-19, 1396/04/28

Ethics committee reference number
KUMS.REC.1396.188

Health conditions studied

1

Description of health condition studied
Recurrent Aphthous Stomatitis

ICD-10 code
K12.0

ICD-10 code description
Recurrent oral aphthae

Primary outcomes

1

Description
duration of healing

Timepoint
healing measurement will be done twice per month

Method of measurement
quantitative and qualitative assays

2

Description
size of lesion

Timepoint
size of lesion measurement will be done twice per month

Method of measurement
quantitative and qualitative assays

3

Description
pain in lesion

Timepoint
pain measurement in lesion will be done twice per month

Method of measurement
quantitative and qualitative assays

4

Description
erythema

Timepoint
erythema evaluation will be done twice per month

Method of measurement
quantitative and qualitative assays

Secondary outcomes

empty

Intervention groups

1

Description
Experimental group: In this group,28 patients will be received 10% Pomegranate gel. The period for use of the product will be twice a day for a period of one month.

Category
Treatment - Drugs

2

Description
Control group: 28 patients will be received placebo. The placebo gels contain all the components of the intervention group gel except for the pomegranate extract; they actually receive the placebo.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Dental clinic
Full name of responsible person
Reza Tahvilian
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Kermanshah University of Medical Science
Full name of responsible person
Reza Tahvilian
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Central building, Beheshti Blvd, Kermanshah University of Medical Science
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice chancellor for research, Kermanshah University of Medical Science
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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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