

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 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

Name

Reza Tahvilian

Name of organization / entity

Kermanshah University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 83 1427 6482

Email address

rtahvilian@kums.ac.ir

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

Street address

School of Pharmacy, Kermanshah University of
Medical Sciences (KUMS) Kermanshah, Iran

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Kermanshah

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

Street address

Central building, Beheshti Blvd, Kermanshah
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Kermanshah

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

School of Pharmacy, Kermanshah University of
Medical Sciences (KUMS) Kermanshah, Iran

Full name of responsible person

Reza Tahvilian

Position

Ph.D

Other areas of specialty/work

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MSc. of Biotechnology

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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