

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 May 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

**City**

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  
University of Medical Science

**City**

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**

**Street address**

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**Web page address**

## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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Fereshte Bagheri

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MSc. of Biotechnology

**Other areas of specialty/work**

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f.bagheri2016@yahoo.com

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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*