

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### A study of the effect of Nigella Sativa oil on control of disease activity and serum levels of IL-10, TNF- $\alpha$ , and oxidative stress markers in patients with Behcet's disease

#### Protocol summary

##### Summary

**Objectives:** The aim of this study is the comparison of the effect of oral administration of Nigella Sativa oil (NSO) and placebo on disease activity and serum levels of oxidative stress markers, and IL-10 and TNF- $\alpha$  cytokines in Behcet's disease (BD). **Design, setting and conduct:** In a randomized double blind study in Connective Tissue Diseases Research Center of Tabriz University of Medical Sciences, 88 patients with BD will recruit to the study. They will divide randomly to the case and control groups. Disease activity of patients will be measured by the Iranian's Behcet's disease activity measure (IBDDAM). **Participants:** Patients with BD. **Inclusion criteria:** age > 16; having active BD (IBDDAM > 2.5). **Exclusion criteria:** consumption of NSO supplements in the past 8 weeks; pregnancy and lactation; Liver disease; renal insufficiency. **Intervention:** case group will receive soft gels containing 1000 mg NSO per day and another group will receive soft gels containing 1000 mg placebo per day. Soft gels containing NSO oil and placebo will be manufactured by the Barij Essence Pharmaceutical Company. All patients will be visited before intervention and every 2 months for 6 months. Before intervention and 2 months after that 10 milliliter blood samples will be taken, centrifuged, and stored at the -70 °C. Plasma levels of TNF- $\alpha$ , IL-10, oxidant and antioxidant systems (total antioxidant, malondialdehyde) will be measured at the end of study. Main outcome measures are disease activity which will be measured by the IBDDAM and plasma levels of TNF- $\alpha$ , IL-10, oxidant and antioxidant systems.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT201511086975N5**

Registration date: **2015-12-12, 1394/09/21**

Registration timing: **prospective**

Last update:

Update count: **0**

##### Registration date

2015-12-12, 1394/09/21

##### Registrant information

###### Name

Alireza Khabbazi

###### Name of organization / entity

Tabriz University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 41 1337 3966

###### Email address

khabbazia@tbzmed.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Tabriz University of Medical Sciences

##### Expected recruitment start date

2016-01-01, 1394/10/11

##### Expected recruitment end date

2017-01-01, 1395/10/12

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

A study of the effect of Nigella Sativa oil on control of

disease activity and serum levels of IL-10, TNF- $\alpha$ , and oxidative stress markers in patients with Behcet's disease

**Public title**

Nigella Sativa oil for treatment of Behcet's disease

**Purpose**

Treatment

**Inclusion/Exclusion criteria**

Inclusion criteria: Age older than 16; Having active Behcet's disease: Iranian's Behcet's Disease Dynamic Activity Measure (IBDDAM) more than 2.5 Exclusion criteria: Consumption of Nigella Sativa oil supplements in the past 8 weeks; Pregnancy and lactation; Liver disease; Renal insufficiency

**Age**

From **16 years** old

**Gender**

Both

**Phase**

1-2

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **88**

**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**

Ethic committee of Tabriz University of Medical Sciences

**Street address**

Four floor, Ethic committee, Vice chancellor for research, Faculty of medicine, Tabriz University of Medical Sciences

**City**

Tabriz

**Postal code**

5166614766

**Approval date**

2015-09-28, 1394/07/06

**Ethics committee reference number**

TBZMED.REC.13940575

**Health conditions studied****1****Description of health condition studied**

Behcet's Disease

**ICD-10 code**

M35.2

**ICD-10 code description**

Behcet's Disease, unspecified

**Primary outcomes****1****Description**

Behcet's disease activity

**Timepoint**

Before, 2, 4, and 6 months after intervention

**Method of measurement**

Iranian's Behcet's disease activity measure

**2****Description**

Plasma levels of TNF- $\alpha$ , IL-10, oxidant and antioxidant systems (total antioxidant, malondialdehyde)

**Timepoint**

Before and 2 months after intervention

**Method of measurement**

Enzyme-Linked Immunosorbent Assay

**Secondary outcomes****1****Description**

Nigella Sativa oil side effects

**Timepoint**

2, 4, and 6 months after intervention

**Method of measurement**

Questionnaire.

**Intervention groups****1****Description**

Case group will receive soft gels containing 1000 mg Nigella Sativa oil per day for 6 months. Soft gels will be used after breakfast.

**Category**

Treatment - Drugs

**2****Description**

Control group will receive soft gels containing 1000 mg (starch) per day for 6 months. Soft gels will be used after breakfast.

**Category**

Treatment - Drugs

## Recruitment centers

1

### Recruitment center

**Name of recruitment center**

Connective Tissue Diseases Research Center, Tabriz  
University of Medical Sciences

**Full name of responsible person**

Alireza Khabbazi

**Street address**

Connective Tissue Diseases Research Center, 4th  
floor, Emam Reza hospital, University street

**City**

Tabriz

## Sponsors / Funding sources

1

### Sponsor

**Name of organization / entity**

Vice chancellor for research, Tabriz University of  
Medical Sciences

**Full name of responsible person**

Hasan Soleimanpoor

**Street address**

Four floor, Vice chancellor for research, Faculty of  
Medicine, Tabriz University of Medical Sciences

**City**

Tabriz

**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, Tabriz 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**

Connective Tissue Diseases Research Center, Tabriz  
University of Medical Sciences

**Full name of responsible person**

Susan kolahi

**Position**

Professor of rheumatology

**Other areas of specialty/work****Street address**

Four floor, Connective Tissue Diseases Research  
Center, Emam Reza Hospital, University street

**City**

Tabriz

**Postal code**

5166614766

**Phone**

+98 41 3337 3966

**Fax****Email**

susan.kolahi@gmail.com

**Web page address**

## Person responsible for scientific inquiries

### Contact

**Name of organization / entity**

Connective Tissue Diseases Research Center, Tabriz  
University of Medical Sciences

**Full name of responsible person**

Alireza Khabbazi

**Position**

Associate professor of rheumatology

**Other areas of specialty/work****Street address**

Connective Tissue Diseases Research Center, Four  
floor, Emam Reza Hospital, University street

**City**

Tabriz

**Postal code**

5167747899

**Phone**

+98 41 3333 2704

**Fax****Email**

khabbazia@tbzmed.ac.ir

**Web page address**

## Person responsible for updating data

### Contact

**Name of organization / entity**

Connective Tissue Diseases Research Center, Tabriz  
University of Medical Sciences

**Full name of responsible person**

Alireza Khabbazi

**Position**

Associate professor of rheumatology

**Other areas of specialty/work****Street address**

Connective Tissue Diseases Research Center, Four  
floor, Emam Reza Hospital, University street

**City**

Tabriz

**Postal code**

5167747899

**Phone**

+98 41 3333 2704

**Fax****Email**

khabbazia@tbzmed.ac.ir

**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*