

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- α , 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- α 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- α , 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- α , 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

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Iran (Islamic Republic of)

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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- α , 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- α , 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

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

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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, 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
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Full name of responsible person

Susan kolahi

Position

Professor of rheumatology

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Person responsible for scientific inquiries

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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