Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 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 ºC. 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

Country

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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

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

City
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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 University of Medical Sciences

Full name of responsible person
Susan kolahi

Position
Professor of rheumatology

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Alireza Khabbazi

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Associate professor of rheumatology

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Person responsible for updating data

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Connective Tissue Diseases Research Center, Tabriz University of Medical Sciences

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Associate professor of rheumatology

Other areas of specialty/work

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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