Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

A placebo- controlled clinical trial to determine the effects of nigella sativa oil extract on selected immune cell markers and oxidative stress in female patients with rheumatoid arthritis

Protocol summary

Summary

The aim of this randomized, placebo-controlled trial is to investigate the effects of nigella sativa oil extract on selected immune cell markers and oxidative stress in rheumatoid arthritis (RA) female patients. Fifty adult patients with RA, diagnosed in accordance with criteria suggested by American College of Rheumatology/European League Against Rheumatism, with mild to moderate disease activity and body mass index less than 40 will be recruited in the study. Patients receiving any non-steroidal anti-inflammatory or disease-modifying more than 10 milligrams per day of anti rheumatic drugs, subjects suffering from inflammatory or metabolic disorders and those with pregnancy or lactation will be excluded. The participants will be assigned into control and treatment groups using permuted-blocks randomization and will receive two 500 milligrams per day soft gels containing paraffin and nigella sativa oil for eight consecutive weeks, respectively. To determine the effects of nigella sativa oil on selected immune cell markers and oxidative stress, disease activity score will be calculated. Also, serum high-sensitivity C-reactive protein, CD4/CD8 ratio, number of CD4+ CD25+ T lymphocytes, interleukin 10, tumor necrosis factor-alpha, malondialdehyde and nitric oxide, catalase and superoxide dismutase levels will be measured using conventional methods at baseline and endpoint of the study in both the groups. Finally, to manage effects of any confounder variables, anthropometric indices, physical activity level and psychological stress status will be measured and a three-day food record will be kept simultaneously with the measurements.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2012120811689N1**
Registration date: **2013-02-12, 1391/11/24**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2013-02-12, 1391/11/24

Registrant information

Name

Sorayya Kheirouri

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

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kheirouris@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice Chancellor of Research, Tabriz University of Medical Sciences

Expected recruitment start date

2013-04-09, 1392/01/20

Expected recruitment end date

2013-07-11, 1392/04/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
A placebo- controlled clinical trial to determine the effects of nigella sativa oil extract on selected immune cell markers and oxidative stress in female patients with rheumatoid arthritis

Public title
The effects of nigella sativa oil on rheumatoid arthritis treatment

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: 1) Subjects diagnosed with rheumatoid arthritis, based on American College of Rheumatology/European League Against Rheumatism (ACR-EULAR) criteria; 2) Patients with mild to moderate rheumatoid arthritis; 3) Under treatment with disease-modifying antirheumatic drugs (Methotrexate, Hydroxychloroquine and Prednisolone less than 10 milligrams per day) and not receiving non-steroidal anti-inflammatory drugs or cytokine inhibitors; 4) Stable medication for at least 2 months prior to the interventions; 5) Have a body mass index (BMI) less than 40; 6) Willing to participate in the study; 7) Ages between 20 and 50. Exclusion criteria: 1) Pregnant and lactating women; 2) Hormone therapy or receiving oral contraceptives; 3) Have diabetes mellitus, thyroid disorders, kidney or hepatic diseases or Cushing's syndrome; 4) Have inflammatory bowel disease or other inflammatory disorders; 5) Taking antioxidant and anti-inflammatory supplements 4 weeks prior to the interventions; 7) Being on a weight reduction diet; 7) Smoking or being exposed to cigarette smoke.

Age
From **20 years** old to **50 years** old

Gender
Female

Phase
2

Groups that have been masked
No information

Sample size
Target sample size: **50**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
In the present study, patients' awareness about their study group may act as a confounder variable on some of outcome measures in particular disease activity scoring. Therefore, the study will be single blinded and all the participants will receive capsules with identical shape, size, and color.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Tabriz University of Medical Sciences

Street address
Golbad Street

City
Tabriz

Postal code

Approval date
2013-01-07, 1391/10/18

Ethics committee reference number
91174

Health conditions studied

1

Description of health condition studied
Rheumatoid arthritis

ICD-10 code
M06.9

ICD-10 code description
Rheumatoid arthritis, unspecified

Primary outcomes

1

Description
Catalase

Timepoint
At baseline and after 8 weeks of intervention

Method of measurement
Spectrophotometry

2

Description
Superoxide dismutase

Timepoint
At baseline and after 8 weeks of intervention

Method of measurement
Spectrophotometry

3

Description
CD4+

Timepoint
At baseline and after 8 weeks of intervention

Method of measurement
flow cytometry

4

Description
CD25+
Timepoint
At baseline and after 8 weeks of intervention
Method of measurement
flow cytometry

5

Description
CD8+
Timepoint
At baseline and after 8 weeks of intervention
Method of measurement
flow cytometry

6

Description
Tumor necrosis factor-alpha (TNF-α)
Timepoint
At baseline and after 8 weeks of intervention
Method of measurement
ELISA

7

Description
Interleukin 10 (IL-10)
Timepoint
At baseline and after 8 weeks of intervention
Method of measurement
ELISA

8

Description
Nitric oxide
Timepoint
At baseline and after 8 weeks of intervention
Method of measurement
Spectrophotometry

9

Description
Malondialdehyde
Timepoint
At baseline and after 8 weeks of intervention
Method of measurement
Spectrophotometry

10

Description
Rheumatoid factor
Timepoint
At baseline and after 8 weeks of intervention
Method of measurement
Autoanalyzer system

11

Description
High-sensitivity C-reactive protein (hs-CRP)
Timepoint
At baseline and after 8 weeks of intervention
Method of measurement
Immunoturbidimetry

12

Description
Disease Activity Score (DAS-28)
Timepoint
At baseline and after 8 weeks of intervention
Method of measurement
calculation based on physical examination and serum hs-CRP

Secondary outcomes

1

Description
Diastolic blood pressure
Timepoint
At baseline and after 8 weeks of intervention
Method of measurement
Stethoscope and sphygmomanometer

2

Description
Systolic blood pressure
Timepoint
At baseline and after 8 weeks of intervention
Method of measurement
Stethoscope and sphygmomanometer

Intervention groups

1

Description
The control group will receive two soft gel capsules containing 500 milligram paraffin as placebo every day for eight consecutive weeks. The placebo preparation process will be conducted in Barij Essence Pharmaceutical Company under established standard protocols. All the patients will receive the placebos on a weekly base and will be monitored for consumption continuation and any possible adverse effects by telephone interviews.
Category
Placebo

2

Description
The case group will receive two soft gel capsules containing 500 milligram of nigella sativa oil extract every day for eight consecutive weeks. The extraction will be conducted by cold press method. Both the

extraction and soft gel making process will be conducted in Barij Essence Pharmaceutical Company under established standard protocols. All the patients will receive the supplements on a weekly base and will be monitored for consumption continuation and any possible adverse effects by telephone interviews.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Sheikholraeis Clinic

Full name of responsible person
Mr. Alizadeh Mohammad

Street address
Sheikholraeis Building, Golgasht crossing, Azadi 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
Dr. Seyed Kazem Shakouri

Street address
Golbad Street

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
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Full name of responsible person
Dr. Sorayya Kheirouri

Position
Assistant professor

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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