Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Formulation and standardization of topical product of Nigella sativa L. and study on its effects in acne vulgaris, a randomized double-blind clinical study

Protocol summary

Study aim
Preparation of standardized topical product of Nigella sativa and study on its efficacy on the patients with acne vulgaris

Design
Randomized double-blind placebo clinical trial

Settings and conduct
56 patients with mild to moderate acne vulgaris will be selected and written informed consent will be obtained, 28patients receive semi-solid preparations of Nigella sativa, and 28patients receive semi-solid preparations of placebo, twice daily for 60 days. It should be noted that both groups of patients receive oral doxycycline as gold standard. To randomly assign the patients to two groups of treatment and placebo by a third person and using a computer program with simple randomization method, the random sample number is generated and each patient will be assigned a number. Even numbers will be allocated to treatment with a semi-solid product from Nigella sativa and odd numbers to placebo. Letter "A" is assigned to the even number and the test drug, and letter "B" is assigned to the odd number and placebo. Patients and the person who provides the drug to patients will be blinded to the drug content.

Participants/Inclusion and exclusion criteria
-Patients between14–35 years and both genders -Mild to moderate acne as defined by the Investigator’s Global Assessment (IGA) scale -Enrolled female participants should have a negative pregnancy test

Intervention groups
28 patients receive semi-solid preparations of Nigella sativa, and 28 patients receive semi-solid preparations of placebo, twice daily for 60 days. It should be noted that both groups of patients receive oral doxycycline as gold standard

Main outcome variables
Improve at least one grade and a maximum of 2 grades in Investigator’s global assessment grading for acne vulgaris

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20180712040449N1**
Registration date: **2018-09-25, 1397/07/03**
Registration timing: **prospective**

Last update: **2018-09-25, 1397/07/03**
Update count: **0**

Registration date
2018-09-25, 1397/07/03

Registrant information

Name
Samaneh Soleymani

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 8899 3656

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S_Soleymani@razi.tums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-10-21, 1397/07/29

Expected recruitment end date
2019-10-20, 1398/07/28

Actual recruitment start date
empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Formulation and standardization of topical product of Nigella sativa L. and study on its effects in acne vulgaris, a randomized double-blind clinical study

Public title

Effect of Nigella sativa on acne vulgaris

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients between 14–35 years old from both genders Patients with mild to moderate acne as defined by the Investigator’s Global Assessment (IGA) scale Enrolled female participants should have a negative pregnancy test

Exclusion criteria:

Any aesthetic facial procedure including laser therapy and tissue/dermal injectables within the last 6 months Patients having wound and infection on face Patients with any skin disorders that might interfere with the diagnosis or evaluation of acne Very severe acne vulgaris Pregnancy or breastfeeding Patients with any uncontrolled systemic disease Using oral isotretinoin in the last 6 months History of hypersensitivity to blackseed

Age

From **14 years** old to **35 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **56**

Actual sample size reached: **34**

Randomization (investigator's opinion)

Randomized

Randomization description

To randomly assign patients to two groups of treatment and placebo by a third person and using a computer program with simple randomization method, the random sample number is generated and each patient will be assigned a number. Even numbers will be allocated to treatment with a semi-solid product, from Nigella sativa and odd numbers to placebo.

Blinding (investigator's opinion)

Double blinded

Blinding description

Even numbers will be allocated to treatment with a semi-solid product from Nigella sativa and odd numbers to placebo. Letter "A" is assigned to the even number and the test drug, and letter "B" is assigned to the odd number and placebo. Patients and the person who provides the drug to patients will be blinded to the drug content.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Vice-Chancellor in Research Affairs of Tehran University of Medical Sciences

Street address

Vice-Chancellor in Research Affairs of Tehran University of Medical Sciences, Ghods Ave, Keshavarz Blvd, Tehran

City

Tehran

Province

Tehran

Postal code

1419814171

Approval date

2018-07-04, 1397/04/13

Ethics committee reference number

IR.TUMS.VCR.REC.1397.244

Health conditions studied

1

Description of health condition studied

Acne Vulgaris

ICD-10 code

L70.0

ICD-10 code description

Acne vulgaris

Primary outcomes

1

Description

People with mild to moderate acne vulgaris

Timepoint

Acne lesions counting at baseline, days 14, 30, and 60

Method of measurement

Investigator’s global assessment grading for acne vulgaris

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: 28 patients receive semi-solid preparations of Nigella sativa, twice daily for 60 days.
Category
Treatment - Drugs

2

Description
Control group: 28 patients receive semi-solid preparations of placebo, twice daily for 60 days.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Reza hospital of Kermanshah University of Medical Science
Full name of responsible person
Samaneh Soleymani
Street address
Parastar Blvd, Kermanshah
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
vice-chancellor in research affairs
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Phone
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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
Tehran University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Samaneh Soleymani
Position
PhD candidate student
Latest degree
Ph.D.
Other areas of specialty/work
Traditional Medicine
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Web page address

http://stpm.tums.ac.ir/

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

The documentation including the primary and secondary outcomes of patients that will be available

When the data will become available and for how long

From the start of the clinical study to one year after the completion of the clinical study

To whom data/document is available

If another researcher wants to perform a clinical study in this field and needs our information to do the study, the information will be provided with confidentiality. - If patients have side effects, and their doctors need the treatment information. -If a health authority's health policy requires our study information, then the information is provided with confidentiality.

Under which criteria data/document could be used

If the applicant is authenticated, his request will be discussed with other researchers involved in the study, and the result will be informed to him.

From where data/document is obtainable

Samaneh Soleymani S_soleymani@razi.tums.ac.ir 0098 21 66976527

What processes are involved for a request to access data/document

At first, the applicants must send their request to the correspond author of the study, whose email address is on the IRCT site, and after verifying the applicant's identity, including one of the upon items, the correspond author requests information of the researchers who are present in the study and is sent to applicants. This period, after the applicant's authentication, will take about two weeks.

Comments