

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Efficacy and safety of *Nigella sativa* cream (20%) vs. tretinoin cream (0.05%) for acne vulgaris: a randomized right/left double-blind comparative clinical trial

Protocol summary

Study aim

This clinical trial aims to compare the effects of black seed cream with tretinoin cream in acne vulgaris

Design

This study is a double-blind randomized clinical trial.

Settings and conduct

This clinical trial will be conducted in The Center for Research and Training in Skin Diseases and Leprosy, and Razi hospital of Tehran University of medical sciences. Participants and healthcare providers will be blind.

Participants/Inclusion and exclusion criteria

Inclusion criteria: individuals aged between 18-50 years old (regardless of gender) diagnosed with mild to moderate facial acne vulgaris (GAGS score ranging from 1 to 30); discontinued any topical or systemic treatments for acne at least 3 months prior to the intervention. Exclusion criteria: women with hirsutism or hormonal problems, pregnancy, breastfeeding, sensitivity to tretinoin or black seed, and candidates for isotretinoin treatment.

Intervention groups

The number of 20 patients participating in this study are considered as 40 half faces, and are allocated into 2 equal groups receiving either tretinoin 0.05% or black seed creams for 8 weeks. Through the treatment period and in the one-month follow-up period, the patients will use identical facial cleansers and sunscreens.

Main outcome variables

Acne lesion counts; reduction of GAGS score; the adverse reactions of the intervention medications.

General information

Reason for update

Firstly, due to COVID pandemic, sample size and treatment duration were decreased, additionally, completing the study took longer time than expected.

Secondly, in order to assess the acne lesions more detailedly, the study took place in The Center of Research and Training in Skin Diseases and Leprosy, in which its equipments (visiopore device, tewameter, corneometer, pHmeter, and mexameter probes) were employed.

Acronym

IRCT registration information

IRCT registration number: **IRCT20191021045173N1**

Registration date: **2020-04-03, 1399/01/15**

Registration timing: **prospective**

Last update: **2022-02-09, 1400/11/20**

Update count: **1**

Registration date

2020-04-03, 1399/01/15

Registrant information

Name

Sarvenaz Zandkarimi

Name of organization / entity

Country

Iran (Islamic Republic of)

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Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-08, 1399/01/20

Expected recruitment end date

2021-03-20, 1399/12/30

Actual recruitment start date

2020-11-01, 1399/08/11

Actual recruitment end date

2021-10-01, 1400/07/09
Trial completion date
 2022-01-05, 1400/10/15

Scientific title
 Efficacy and safety of Nigella sativa cream (20%) vs. tretinoin cream (0.05%) for acne vulgaris: a randomized right/left double-blind comparative clinical trial

Public title
 Black seed vs. Tretinoin in acne vulgaris

Purpose
 Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 Age between 18-50 years Clinical diagnosis of mild to moderate facial acne (GAGS score ranging from 1 to 30) made by a dermatologist Discontinuation of any topical or systemic treatment for acne from at least 3 months prior to participation
Exclusion criteria:
 Pregnancy or lactation, Women with hirsutism, menstrual disorders and hormonal problems, Severe grade of acne, Candidate for isotretinoin treatment, Known allergy to black seed or tretinoin, Subjects who are non-cooperative or unsatisfied with the treatment

Age
 From **18 years** old to **50 years** old

Gender
 Both

Phase
 2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
 Target sample size: **40**
 More than 1 sample in each individual
 Number of samples in each individual: **2**
 One half of the face will receive tretinoin cream while in the other half, black seed cream will be applied.
 Actual sample size reached: **20**
 More than 1 sample in each individual
 Actual sample size in each individual: **2**
 One half of the face received tretinoin cream, and the other half, back seed cream

Randomization (investigator's opinion)
 Randomized

Randomization description
 Treatment tubes were randomly labeled by a third party not involved in the study from 1 to 40 so that the tubes with odd numbers contained NS 20% cream and the ones with even numbers contained tretinoin 0.05% cream. The 20 patients were considered as 40 half faces and were randomly allocated into two comparison groups. Simple randomization procedure with an 1 : 1 allocation ratio was performed as following: subjects with odd admission numbers were supposed as 'right half-face: odd-numbered tube' (group I) and the ones with even

admission numbers were assumed as 'left half-face: odd-numbered tube' (group II). In each case, the reverse half-face was given an even-numbered tubes.

Blinding (investigator's opinion)
 Double blinded

Blinding description
 Treatment tubes were randomly labeled by a third party not involved in the study from 1 to 40 so that the tubes with odd numbers contained NS 20% cream and the ones with even numbers contained tretinoin 0.05% cream.

Placebo
 Not used

Assignment
 Parallel

Other design features

Secondary Ids
 empty

Ethics committees

1

Ethics committee

Name of ethics committee
 Ethics committee of Tehran Islamic Azad University of Medical Sciences

Street address
 Faculty of pharmacy, Islamic Azad University of Medical Sciences, Yasaman Alley, Yakhchal Street, District 1, Tehran.

City
 Tehran

Province
 Tehran

Postal code
 1941933111

Approval date
 2019-12-04, 1398/09/13

Ethics committee reference number
 IR.IAU.TMU.REC.1398.171

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
 Acne lesion counts

Timepoint
 Baseline (before intervention) and 4 , 8 weeks after

intervention, and one month after discontinuation of treatments (the 12th week after baseline)

Method of measurement

Independent assessment of lesion counts: comedones, papules/pustules

2

Description

Reduction of Global Acne Grading System (GAGS) score

Timepoint

Baseline (before intervention) and 4 , 8 weeks after intervention, and one month after discontinuation of treatments (the 12th week after baseline)

Method of measurement

Rating of acne according to Global Acne Grading System (GAGS) by two dermatologists

3

Description

Patients satisfaction

Timepoint

4 , 8 weeks after intervention, and one month after discontinuation of treatments (the 12th week after baseline)

Method of measurement

Patient subjective satisfaction score ranging from 1 to 100

4

Description

Adverse reactions of the study medications

Timepoint

4 , 8 weeks after intervention, and one month after discontinuation of treatments (the 12th week after baseline)

Method of measurement

Patients reports and clinical assessments by two dermatologists

5

Description

Photographic assessment

Timepoint

Baseline (before intervention) and 4 , 8 weeks after intervention, and one month after discontinuation of treatments (the 12th week after baseline)

Method of measurement

Digital camera

6

Description

Visiopore parameters (quantity, size, and value)

Timepoint

Baseline (before intervention) and 4 , 8 weeks after intervention, and one month after discontinuation of treatments (the 12th week after baseline)

Method of measurement

Visiopore device

7

Description

skin hydration

Timepoint

Baseline (before intervention) and 4 , 8 weeks after intervention, and one month after discontinuation of treatments (the 12th week after baseline)

Method of measurement

Corneometer probe

8

Description

skin erythema

Timepoint

Baseline (before intervention) and 4 , 8 weeks after intervention, and one month after discontinuation of treatments (the 12th week after baseline)

Method of measurement

mexameter probe

9

Description

skin melanin

Timepoint

Baseline (before intervention) and 4 , 8 weeks after intervention, and one month after discontinuation of treatments (the 12th week after baseline)

Method of measurement

mexameter probe

10

Description

Transepidermal water loss

Timepoint

Baseline (before intervention) and 4 , 8 weeks after intervention, and one month after discontinuation of treatments (the 12th week after baseline)

Method of measurement

Tewameter probe

11

Description

Skin pH

Timepoint

Baseline (before intervention) and 4 , 8 weeks after intervention, and one month after discontinuation of treatments (the 12th week after baseline)

Method of measurement

pHmeter probe

Secondary outcomes

empty

Intervention groups

1

Description

20 patients are considered as 40 half faces ,and 2 comparison groups are designed as 20 right and 20 left half faces in order to omit the interindividual differences and compare each participant responses to the medications with her/himself. Patients will be individually instructed to apply a thin layer of the given topical medications which are labelled as "left" and "right" on the determined side of the clean facial skin for 8 weeks as twice daily administration. Through the treatment period and the one-month follow-up period, the patients will use identical facial cleansers and sunscreens.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Center for Research & Training in Skin Diseases & Leprosy

Full name of responsible person

Dr. Alireza Firooz

Street address

The Center for Research and Training in Skin Diseases and Leprosy, No. 415, Naderi St., Taleghani Ave.

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2

Recruitment center

Name of recruitment center

Razi Hospital

Full name of responsible person

Dr. Maryam Daneshpazhooh

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr. Farshad Hashemian

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Department of Clinical Pharmacy, Pharmaceutical Sciences Branch, Islamic Azad University, PO Box 19419, Yasaman St, Yakhchal Ave, Qolhak Ave, Shariati Ave, Tehran, Iran

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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

Islamic Azad University

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

Islamic Azad University

Full name of responsible person

Dr. Mehdi Rajabi

Position

Assistant professor

Latest degree

Specialist

Other areas of specialty/work

Clinical pharmacy

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Dr. Zahra Azizian
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Latest degree
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Other areas of specialty/work
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Person responsible for updating data

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Name of organization / entity
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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be 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

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

Title and more details about the data/document

Only the data related to the measured outcomes will be
published

When the data will become available and for how long

Availability starts after publication

To whom data/document is available

Available for people working in academic institutions

Under which criteria data/document could be used

Applicants ought to send a request email containing their
aims and how the data will be used to the given gmail
address

From where data/document is obtainable

contact: Sarvenazkarimi96@gmail.com

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

After assessment of the applicant's request, if agreed,
the data files will be sent in the shortest possible time .

Comments