Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jun 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 balck 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 pandemy, 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

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Iran (Islamic Republic of)

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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

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Recruitment center

Name of recruitment center
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Full name of responsible person
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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Full name of responsible person
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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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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 aught 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