Clinical Trial Protocol
Iranian Registry of Clinical Trials

26 Aug 2026

Investigating the Therapeutic Effect of Nigella Sativa in Male Genital Wart: A Randomized, Double-Blind Clinical Trial

Protocol summary

Study aim

This study is designed to evaluate the topical therapeutic effect of Nigella sativa oil on male anogenital warts in comparison with the standard 5% imiquimod treatment.

Design

This study is a double-blind, randomized controlled trial with a sample size of 60 participants. Randomization will be performed using block and cluster randomization via the online randomization software, Research Randomizer.

Settings and conduct

This study will be conducted at the Papilloma Clinic of shahid Motahari Hospital. Eligible patients clinically diagnosed with genital warts by the infectious disease specialist will be enrolled after meeting the inclusion/exclusion criteria and providing written informed consent. both the participating patients and the infectious disease specialist responsible for patient examination and follow-up will be blinded to the type of treatment (intervention or placebo) administered to the patients.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: 18 -60 male No past history of immune suppressive disease No concurrent sexually transmitted diseases Genital warts <1 cm diameter No prior the human papillomavirus vaccination

Intervention groups

The intervention group applies Imiquimod 5% cream three times a week at night before sleep to the affected area, and after 8 hours the site is washed with water and soap. In addition, Nigella sativa oil is applied to the warts three times daily in the morning, at noon, and in the evening. The treatment continues until complete disappearance of the lesions or for a maximum of 16 weeks. For this purpose, the standardized Nigella sativa oil product of Barij Essence Company with the health code 6713905054496688 is used. The control group will similarly receive placebo until the end of the study.

Main outcome variables

Size of warty lesions, Number of warty lesions, Side effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20251103067866N1**
Registration date: **2026-01-25, 1404/11/05**
Registration timing: **prospective**

Last update: **2026-01-25, 1404/11/05**
Update count: **0**

Registration date

2026-01-25, 1404/11/05

Registrant information

Name

Mozaffar Rezvani zadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 5597 3051

Email address

mozaffar.rezvani.72@gmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-04-20, 1405/01/31

Expected recruitment end date

2027-06-20, 1406/03/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Investigating the Therapeutic Effect of Nigella Sativa in Male Genital Wart: A Randomized, Double-Blind Clinical Trial

Public title
Investigating the Effect of Nigella Sativa in Male Genital Wart

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
18 -60 male No past history of immune suppressive disease No concurrent sexually transmitted diseases Genital warts <1 cm diameter No prior human papillomavirus vaccination

Exclusion criteria:
People with a history of allergy to Nigella Sativa

Age
From **18 years** old to **60 years** old

Gender
Male

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be allocated into two groups of 30 using block randomization with a block size of four. All six possible combinations of A and B will be considered, and the random allocation sequence will be generated by a statistician using Random Allocation Software. A randomization table will be prepared, and the principal investigator will be blinded to the allocation sequence. Participants will be assigned to intervention groups according to the randomization table in the order of enrollment.

Blinding (investigator's opinion)
Double blinded

Blinding description
This study will be conducted as a double-blind trial. The intervention drug (Nigella sativa oil) and the placebo (pharmaceutical-grade paraffin oil) will be identical in appearance, color, odor, volume, and packaging, and will be provided in identical containers labeled with anonymous codes. Coding of the study medications will be performed based on the random allocation table generated by a statistician, and the code list will be kept secure until completion of data analysis. Throughout the study, participants, the principal investigator, and all outcome assessors will remain unaware of the assigned intervention groups. Unblinding will be performed only after completion of data collection and final data analysis.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
The Ethics Committee of Iran University of Medical Sciences

Street address
Iran University of Medical Sciences, Hemmat Highway

City
Tehran

Province
Tehran

Postal code
۱۴۴۹۶۱۴۵۳۵

Approval date
2025-09-17, 1404/06/26

Ethics committee reference number
IR.IUMS.REC.1404.629

Health conditions studied

1

Description of health condition studied
Genital Wart

ICD-10 code
A63.0

ICD-10 code description
Anogenital (venereal) warts

Primary outcomes

1

Description
Size of warty lesions

Timepoint
Before and after the completion of the intervention

Method of measurement
The primary outcome is assessed clinically and documented by measuring size changes using a ruler.

2

Description
Number of warty lesions

Timepoint

Before and after the completion of the intervention

Method of measurement

Lesions are observed and counted through clinical examination.

3

Description

Side effects

Timepoint

Before the intervention and 2 weeks after the completion of the intervention

Method of measurement

Yellow form for reporting adverse drug reactions

Secondary outcomes

empty

Intervention groups

1

Description

The intervention group applies imiquimod 5% topically three times per week on alternate nights before bedtime. The application area is washed with soap and water approximately 8 hours later. Additionally, they use black seed oil three times a day – in the morning (after washing off the imiquimod), at noon, and in the evening .Patients are advised to apply a thin layer of the standardized black seed oil product (Barij Essence Company, health code: 6713905054496688) on the volar surface of the forearm 24 hours prior to initiating treatment. The application site should be monitored for signs such as redness, itching, burning, or swelling. If local adverse effects occur, the patient will be withdrawn from the study (and replaced by another participant) and will receive appropriate guidance for further management. The treatment continues until complete disappearance of the lesions or for a maximum of 16 weeks.

Category

Treatment - Drugs

2

Description

The control group applies Imiquimod 5% cream three times a week at night before sleep to the affected area, and after 8 hours the site is washed with water and soap. In addition, instead of Nigella sativa oil, the placebo is applied three times daily in the morning, at noon, and in the evening after the lesion site has been cleaned of the 5% Imiquimod cream, that is, in the morning after washing the area, and at noon and in the evening, to the wart. The placebo is prepared with pharmaceutical-grade paraffin oil by Barij Essence Company. Patients are advised to apply a thin layer of the placebo product on the anterior forearm 24 hours before starting treatment and examine the area for symptoms such as redness, itching, burning, and swelling. In case of local adverse reactions, the patient will be excluded from the study (and replaced with another person), and the necessary guidance will be provided for continuation of treatment. The treatment continues until complete disappearance of the lesions or for a maximum of 16 weeks.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Motahari hospital- Papilloma clinic

Full name of responsible person

Maryam Taghavi Shirazi

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Behesht Ave., School of Persian Medicine

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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

Iran 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
Iran University of Medical Sciences
Full name of responsible person
Mozaffar Rezvani Zadeh
Position
Resident
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Other areas of specialty/work
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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be 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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be 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