Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Preparation of sticky mucus gel containing Nigella sativa extract, comparison and evaluation of its clinical effect with Clotrimazole vaginal cream 1% for the treatment of vulvovaginal candidiasis.

Protocol summary

Study aim
Preparation of vaginal mucus gel based on carbomer and hydroxypropyl cellulose containing Nigella sativa extract to treat vulvovaginal candidiasis. Comparison of the treatment effect of vaginal sticky mucus gel containing black seed extract with Clotrimazole 1% cream treatment in patients with vulvovaginal candidiasis referred to Ayatollah Mousavi Hospital in Zanjan.

Design
Among the people referred to Ayatollah Mousavi Hospital, we study 102 people with vaginal candidiasis.

Settings and conduct
Patients with vaginal candidiasis referring to Ayatollah Mousavi Hospital are studied. The purpose of this study is to compare the clinical effect of vaginal mucus gel containing black seed extract with Clotrimazole 1% cream. The study is three-way blind.

Participants/Inclusion and exclusion criteria
Inclusion criteria: reproductive age (15 to 45 years), presence of clinical symptoms of vulvovaginal candidiasis, lack of sensitivity to black seed Exclusion criteria: pregnant women, allergy to nigella, diabetes, corticosteroid use, antibiotic use in the last two weeks

Intervention groups
Intervention group: vaginal candidiasis patients who receive vaginal mucus gel containing black seed extract. Control group: vaginal candidiasis patients who receive Clotrimazole 1% cream.

Main outcome variables
Vaginal candidiasis

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20220510054813N1**
Registration date: **2023-03-16, 1401/12/25**
Registration timing: **prospective**

Last update: **2023-03-16, 1401/12/25**
Update count: **0**

Registration date
2023-03-16, 1401/12/25

Registrant information

Name
Shabnam Towfighi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 24 3374 2459

Email address
shabnam.towfighi@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-04-04, 1402/01/15

Expected recruitment end date
2024-01-05, 1402/10/15

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Preparation of sticky mucus gel containing Nigella sativa extract, comparison and evaluation of its clinical effect with Clotrimazole vaginal cream 1% for the treatment of vulvovaginal candidiasis.

Public title
Preparation of sticky mucus gel containing Nigella sativa extract, comparison and evaluation of its clinical effect with Clotrimazole vaginal cream 1% for the treatment of vulvovaginal candidiasis.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Presence of clinical symptoms of vulvovaginal candidiasis Insensitivity to Nigella sativa
Exclusion criteria:
diseases such as diabetes pregnancy Allergy to nigella sative Cortone use Taking antibiotics in the last two weeks
Age
From **15 years** old to **45 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider
- Data analyser

Sample size
Target sample size: **102**
Randomization (investigator's opinion)
Randomized
Randomization description
We will use a simple randomization method
Blinding (investigator's opinion)
Triple blinded
Blinding description
In this study, those responsible for data collection and those who evaluate the outcome and the patient themselves will be completely unaware of the treatment protocol.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Zanjan University of Medical Sciences
Street address
Zanjan University of Medical Sciences, Jomhori BLV. Azadi Squ. Zanjan
City
Zanjan
Province
Zanjan
Postal code
1435689752
Approval date
2023-01-08, 1401/10/18
Ethics committee reference number
IR.ZUMS.REC.1401.283

Health conditions studied

1

Description of health condition studied
Vaginal candidiasis
ICD-10 code
B37.3
ICD-10 code description
Candidiasis of vulva and vagina

Primary outcomes

1

Description
In this study, after filling the written informed consent form, the person is examined. People diagnosed with vulvovaginal candidiasis (Candida albicans); Randomly, one group will be given vaginal gel with sticky black seed and one group will be given Clotrimazole 1% cream in the same package, which patients should use once every night for a week through an applicator. After a week, patients return for re-examination, which is checked for improvement of symptoms and clinical examination.
Timepoint
One week after starting treatment
Method of measurement
Examination of clinical symptoms such as secretions, itching, inflammation and odor

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: People who receive sticky mucus gel containing black seed extract.
Category
Treatment - Drugs

2

Description
Control group: People who receive clotrimazole 1% cream.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Ayatollah Mousavi Hospital in Zanjan
Full name of responsible person
shabnam Towfighi
Street address
Ayatollah Mousavi Hospital, Gavazang Road, Zanjan
City
Zanjan
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1425678922
Phone
+98 21 8806 4148
Email
shabnam.towfighi@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Zanjan University of Medical Sciences
Full name of responsible person
samad nadri
Street address
Zanjan University of Medical Sciences Campus, Dr. Yousef Sabouti Blvd., Zanjan
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Zanjan
Postal code
4513956184
Phone
+98 24 3301 8100
Email
riasat@zums.ac.ir
Web page address

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zanjan 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
Zanjan University of Medical Sciences
Full name of responsible person
shabnam Towfighi
Position
Non-faculty specialist physician
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
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Ayatollah Mousavi Hospital, Gavazang Road, Zanjan
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Person responsible for scientific inquiries

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Person responsible for updating data

Contact

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Position
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Latest degree
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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
Yes - There is 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
Part of the data including the main and secondary outcomes can be shared.
When the data will become available and for how long
Access period starts from 2023
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
Raw data is not available to individuals and upon request, the results of the requested statistical analysis will be available to individuals.
From where data/document is obtainable
.
What processes are involved for a request to access data/document
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Comments