

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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 sativa 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 Zanzan University of Medical Sciences

##### Street address

Zanzan University of Medical Sciences, Jomhori BLV. Azadi Squ. Zanzan

##### City

Zanzan

#### Province

Zanzan

#### 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

**Province**

Zanjan

**Postal code**

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

**City**

Zanjan

**Province**

Zanjan

**Postal code**

4513956184

**Phone**

+98 24 3301 8100

**Email**

riasad@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

**Street address**

Ayatollah Mousavi Hospital, Gavazang Road, Zanjan

**City**

Zanjan

**Province**

Zanjan

**Postal code**

1425678922

**Phone**

+98 21 8806 4148

**Email**

shabnam.towfighi@gmail.com

## Person responsible for scientific 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

**Street address**

Ayatollah Mousavi Hospital, Gavazang Road, Zanjan

**City**

Zanjan

**Province**

Zanjan

**Postal code**

1425678922

**Phone**

+98 21 8806 4148

**Email**

shabnam.towfighi@gmail.com

## Person responsible for updating data

#### 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

**Street address**

Ayatollah Mousavi Hospital, Gavazang Road, Zanjan

**City**

Zanjan

**Province**

Zanjan

**Postal code**

1425678922

**Phone**

+98 21 8806 4148

**Email**

shabnam.towfighi@gmail.com

**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****Comments**