Clinical Trial Protocol
Iranian Registry of Clinical Trials

11 Jul 2026

Evaluation of the effectiveness of topical application of special emulsion for epithelial tissue prepared with black seed oil in the treatment of vulvovaginal mucositis

Protocol summary

Study aim
Evaluation of the effectiveness of topical application of black seed oil emulsion in the treatment of inflammation of the vaginal mucosa

Design
Clinical trial with control group, with parallel groups, double-blind, phase 3 per 100 patients, Covariate Adaptive method was used for randomization

Settings and conduct
This research will be performed in the treatment clinics of Alborz University of Medical Sciences. The researcher will first perform a biopsy and history and then the patient will be clinically examined. Inside the cervix, examine the vaginal cavity for inflammation, redness, and discharge in shape, color, odor, and consistency, and if vulvovaginitis is confirmed, the required samples will be selected. After obtaining informed consent from the samples, the researcher completes the questionnaire and the patient receives the necessary instructions according to being placed in intervention groups 1, 2 or control

Participants/Inclusion and exclusion criteria
Inclusion criteria: age 15-60 years, no use of immunosuppressive drugs, antibiotics and topical creams and ointments during the last week, not pregnant and breastfeeding, normal Pap smear test / Exclusion criteria: sensitivity to the drug prescribed to the patient, no Follow the treatment regularly and according to the instructions, mandatory prescription of antibiotics by another doctor, having sex with multiple partners during the treatment period

Intervention groups
In intervention group 1, topical spray made of black seed oil emulsion with a dose of 1% for 7 days and 2 times a day and in intervention group 2, topical spray made of 1% vegetable oil emulsion with antibiotics are used. The control group is treated with the antibiotic prescribed by the doctor (single dose of metronidazole or single dose of fluconazole)

Main outcome variables
Inflammation of the vulvovaginal mucosa

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20200720048145N2**
Registration date: **2020-09-07, 1399/06/17**
Registration timing: **prospective**

Last update: **2020-09-07, 1399/06/17**
Update count: **0**

Registration date
2020-09-07, 1399/06/17

Registrant information

Name
Mohammad Reza Maghsoudi

Name of organization / entity
Alborz University Of Medical Sciences

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-09-19, 1399/06/29

Expected recruitment end date
2020-11-19, 1399/08/29

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effectiveness of topical application of special emulsion for epithelial tissue prepared with black seed oil in the treatment of vulvovaginal mucositis

Public title
Evaluation of the effectiveness of black seed oil in the treatment of vulvovaginal mucositis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 15-60 years Do not using immunosuppressive drugs, antibiotics and topical creams and ointments during the last week Do not be pregnant or breastfeeding Normal Pap smear test
Exclusion criteria:
Allergy to the drug prescribed to the patient Failure to follow treatment regularly and as directed Mandatory administration of antibiotics by another physician outside the scope of the present study Having sex with multiple partners during treatment
Age
From **15 years** old to **60 years** old
Gender
Female

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
A form has been prepared for the physician to divide the samples into intervention and control groups, which has a table in which the number of samples in the two intervention groups and a control group based on confounding variables of age, sex, sex and anatomical anomalies It is located in three separate rows and after placing the first sample in the table, the other samples will be placed in the group with the lowest number of samples after summing the number of samples in the intervention and control groups
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Alborz University of Medical Sciences
Street address
Safarian Ave,Golshahr Ave,Alborz Medical Sciences Research and Technology Deputy
City
Karaj
Province
Alborz
Postal code
3198764653
Approval date
2020-08-21, 1399/05/31
Ethics committee reference number
IR.ABZUMS.REC.1399.127

Health conditions studied

1

Description of health condition studied
Inflammation of the vulvovaginal mucosa
ICD-10 code
N77.1
ICD-10 code description
Vaginitis, vulvitis and vulvovaginitis in diseases classified elsewhere

Primary outcomes

1

Description
Inflammation of the vagina
Timepoint
In two stages before the intervention and after the intervention
Method of measurement
Examination of the vagina

Secondary outcomes

1

Description
Vaginal discharge
Timepoint
Before and 7 days after the start of the intervention
Method of measurement
Questionnaire

2

Description
Vaginal itching
Timepoint
Before and 7 days after the start of the intervention
Method of measurement
Questionnaire

3

Description
Bad smell of vaginal discharge
Timepoint
Before and 7 days after the start of the intervention
Method of measurement
Questionnaire

4

Description
Vaginal burning
Timepoint
Before and 7 days after the start of the intervention
Method of measurement
Questionnaire

5

Description
Painful intercourse
Timepoint
Before and 7 days after the start of the intervention
Method of measurement
Questionnaire

6

Description
Urinary incontinence
Timepoint
Before and 7 days after the start of the intervention
Method of measurement
پرسشنامه

Intervention groups

1

Description
Intervention group: Patients use topical spray made from black seed oil emulsion at a dose of 1% twice a day at a dose of 2 puffs for 7 days
Category
Treatment - Drugs

2

Description
Intervention group: Patients use topical spray made from emulsion of 1% vegetable oils for 7 days, 2 times a day at a dose of 2 puffs and antibiotics prescribed by a doctor for 7 days once a day.
Category
Treatment - Drugs

3

Description
Control group: Patients will be treated with antibiotics prescribed by a physician (single dose of metronidazole 250 mg in bacterial vaginitis and trichomoniasis and single dose of fluconazole 100 mg in candidal vaginitis)
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
EmamAli Hospital
Full name of responsible person
Mohammad Reza Maghsoudi
Street address
Azimiyeh,EmamAli Hospital
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Sponsors / Funding sources

1

Sponsor
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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
Alborz 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
Alborz University of Medical Sciences
Full name of responsible person
Mohammad Reza Maghsoudi
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Emergency Medicine
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Person responsible for updating data

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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
Not applicable
Data Dictionary
Not applicable