Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

Evaluation of the effects of topical application of micro emulsion prepared with black seed oil carrier of lipophilic active ingredients in the treatment of inflammatory disorders of Vulva vagina cavity

Protocol summary

Study aim
Evaluation of the effects of topical application of micro emulsion prepared with Black seed oil carrier of lipophilic active ingredients in the treatment of inflammatory disorders of vulva vaginal cavity.

Design
Clinical trial with control group and two intervention groups 1 and 2, three blind strains, non-randomized, phase 2-3, on 99 patients, uses the Covariate Adaptive Randomization (CAR) method to distribute confounding variables to the study groups..

Settings and conduct
The research will perform in the hospitals clinic of Alborz University of Medical Sciences. After taking a history, the Obstetricians specialist examines the patients and according to the conditions for entering the research selects the desired samples in case of a definite diagnosis of rhinosinusitis. After introducing and obtaining consent according to the CAR method, patients are placed in one of the three intervention groups and patients are evaluated in several stages. The letters A and B are used on the drugs, so the analyzer, patients and physician are not aware of the treatment method.

Participants/Inclusion and exclusion criteria
Inclusion criteria include all patients with vulvovaginitis over the age of 15 and under 60 years old, not using special drugs during the last week, normal Pap smear test as well as exclusion criteria include patients with allergie to natural products and placement during pregnancy and lactation period.

Intervention groups
Patients are intervened in three groups. In the control group, patients are treated with conventional oral tablets. In intervention group 1 Patients are treated with a topical solution containing micro emulsion made with flaxseed oil with conventional oral tablets. In intervention group 2 patients are treated with topical solution containing micro emulsion of black seed oil.

Main outcome variables
Inflammation of the mucosa of the vulva vaginal cavity

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210421051030N2**
Registration date: **2021-08-27, 1400/06/05**
Registration timing: **retrospective**

Last update: **2021-08-27, 1400/06/05**
Update count: **0**

Registration date
2021-08-27, 1400/06/05

Registrant information

Name
Behnam Mokri Savojbolaghi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 21 0000 0000

Email address
bms1909@iran.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-08-14, 1400/05/23

Expected recruitment end date
2021-08-20, 1400/05/29

Actual recruitment start date
empty

Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluation of the effects of topical application of micro emulsion prepared with black seed oil carrier of lipophilic active ingredients in the treatment of inflammatory disorders of Vulva vagina cavity

Public title
Evaluation of the effects of solution made with black seed oil in the treatment of vulvovaginitis
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All vulvovaginitis patients over 15 years of age and under 60 years of age Not used immunosuppressive and antibiotics drugs during the last week Normal Pap smear test
Exclusion criteria:
Sensitivity to natural products Placement during pregnancy and lactation
Age
From **15 years** old to **60 years** old
Gender
Female

Phase
2-3
Groups that have been masked

- Participant
- Investigator
- Data and Safety Monitoring Board

Sample size
Target sample size: **99**
Randomization (investigator's opinion)
Not randomized
Randomization description
Blinding (investigator's opinion)
Triple blinded
Blinding description
the researcher In order to blind the research for the patients and the treating physician, has prepared both samples of the drug and placebo in the same form so that they are not aware of the type of drug and placebo treatment. Sprays containing black seed oil micro emulsion and spray containing normal isotonic saline (placebo) in similar pumped bottles were marked with A and B marks, respectively. Also, oral antibiotic tablets and placebo tablets with A and B marks were placed in similar cans, respectively. The project clinical assistant then delivers the sprays and tablets, pre-marked A and B, based on the group that the patient has been categorized by sampling method. Also, the collected data with the same abbreviations A and B are delivered to the analyzer to be realized in the third strain of blinding.
Placebo
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
Deputy of Research and Technology, Saffarian Alley, 45 meters of Golshahr
City
Karaj
Province
Alborz
Postal code
3198764653
Approval date
2021-06-19, 1400/03/29
Ethics committee reference number
IR.ABZUMS.REC.1400.107

Health conditions studied

1

Description of health condition studied
Vulvovaginitis
ICD-10 code
N76
ICD-10 code description
Other inflammation of vagina and vulva

Primary outcomes

1

Description
Inflammation of the mucosa of the vulva vaginal cavity
Timepoint
Before the intervention, During the intervention, after the intervention, one week after the intervention
Method of measurement
Visual Analogue Scale (Measure by Yes or No)

Secondary outcomes

1

Description
Purulent vaginal discharge
Timepoint
Before the intervention, one week after the intervention
Method of measurement

Questionnaire (Based on patient self-expression)

2

Description
Vaginal itching
Timepoint
Before the intervention, one week after the intervention
Method of measurement
Questionnaire (Based on patient self-expression)

3

Description
Vaginal burning
Timepoint
Before the intervention, one week after the intervention
Method of measurement
Questionnaire (Based on patient self-expression)

4

Description
Malodor
Timepoint
Before the intervention, one week after the intervention
Method of measurement
Questionnaire (Based on patient self-expression)

5

Description
Painful intercourse
Timepoint
Before the intervention, one week after the intervention
Method of measurement
Questionnaire (Based on patient self-expression)

6

Description
Urine itching (Dysuria)
Timepoint
Before the intervention, one week after the intervention
Method of measurement
Questionnaire (Based on patient self-expression)

7

Description
Swelling of the mucosa
Timepoint
Before the intervention, one week after the intervention
Method of measurement
Examination

8

Description
Redness of the mucosa
Timepoint
Before the intervention, one week after the intervention
Method of measurement
Examination

9

Description
Mucosal lesions
Timepoint
Before the intervention, one week after the intervention
Method of measurement
Examination

10

Description
Mucosal ulcers
Timepoint
Before the intervention, one week after the intervention
Method of measurement
Examination

Intervention groups

1

Description
Control group: the patients will treat by oral tablets (single dose of metronidazole 250 mg in bacterial vulvovaginitis and trichomoniasis and single dose of fluconazole 100 mg in candidate vulvovaginitis). They also receive a solution containing normal saline isotonic as a placebo made by BMS scientific and research group.
Category
Treatment - Drugs

2

Description
Intervention group 1: the patients will treat by a topical solution containing micro emulsion prepared with black seed oil made by BMS scientific and research group plus oral tablets (single dose of metronidazole 250 mg in bacterial vulvovaginitis and trichomoniasis and single dose of fluconazole 100 mg in candida vulvovaginitis).
Category
Treatment - Drugs

3

Description
Intervention group 2: the patients will treat by a topical solution containing black seed oil micro emulsion and placebo oral tablets made by BMS scientific and research group.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Kamali Hospital
Full name of responsible person
Bita Badenosh

Street address
Shohada square ,Kamali st, Kamali educational and medical center
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Alborz University of Medical Science
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?
No
Title of funding source
BMS science and research group
Proportion provided by this source
100
Public or private sector
Private
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact
Name of organization / entity
Iran University of Medical Sciences
Full name of responsible person
Behnam Mokri Savojbolaghi
Position
Clerk
Latest degree
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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

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