Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Evaluation of the effectiveness of Thymol vaginal cream on improving symptoms in patients with bacterial vulvovaginitis; A double-blind randomized clinical trial

Protocol summary

Study aim
Evaluating the effectiveness of thymol vaginal cream on improving symptoms in patients with bacterial vulvovaginitis

Design
A clinical trial with a control group, with a parallel group, double-blind, randomized, phase two, on 60 patients. Random using the RND function of Excel software

Settings and conduct
Venue: Yazd Research Institute of Reproductive Sciences How to conduct: The study will be conducted on 60 patients with bacterial vulvovaginitis (Trichomonas vaginalis) (diagnosis based on clinical examination or testing of vaginal secretions). Patients are randomly divided into intervention (thymol) and control (metronidazole) groups. Medicinal items will be placed in sealed and numbered boxes at the disposal of doctors and patients. Patients will be evaluated on days 1-3-7.

Participants/Inclusion and exclusion criteria
Married women with bacterial vulvovaginitis

Intervention groups
Patients with bacterial vulvovaginitis in one group were treated with topical thymol vaginal cream and in the other group were treated with metronidazole tablets.

Main outcome variables
Clinical complaints (itching, foul-smelling discharge, vaginal irritation and burning, pain during intercourse, and pain in the lower abdomen) Clinical observations (inflammation of the appearance of the cervix, inflammation of the appearance of the vagina, homogeneity of secretions, abnormality of the amount of secretions, and the color of secretions) The occurrence of complications

General information

Reason for update
The ethics code was entered incorrectly, and now the correct code is registered.

Acronym

IRCT registration information
IRCT registration number: **IRCT20191106045356N12**
Registration date: **2022-08-14, 1401/05/23**
Registration timing: **prospective**

Last update: **2022-10-08, 1401/07/16**
Update count: **1**

Registration date
2022-08-14, 1401/05/23

Registrant information

Name
Mohsen Zabihi

Name of organization / entity

Country
Iran (Islamic Republic of)

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+98 35 3820 3865

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mzabihi100@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-08-23, 1401/06/01

Expected recruitment end date
2022-11-22, 1401/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effectiveness of Thymol vaginal cream on improving symptoms in patients with bacterial vulvovaginitis; A double-blind randomized clinical trial

Public title
Evaluation of the effects of thymol vaginal cream on bacterial vulvovaginitis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Female Married Patients with bacterial vulvovaginitis based on ASMEL criteria Willingness to participate in the study and complete the ethical consent form

Exclusion criteria:
Irritation or allergic reaction to the drug Aggravation of symptoms caused by infection Not taking medicine for more than one day Women who are pregnant, breastfeeding, have immune deficiency or malignancy History of mental disorders and psychosis Allergic reactions following consumption of thymol or products containing thymol

Age
From **18 years** old to **50 years** old

Gender
Female

Phase
2-3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomization method: Block randomization (patients will be selected in blocks of 5) Randomization Unit: Person Randomization tool: Sealed envelopes To concealing random allocation will use Sequentially numbered, sealed, opaque envelopes (SNOSE).

Blinding (investigator's opinion)
Double blinded

Blinding description
The study will be done in a double-blind manner. Patients, clinical caregiver (doctor) and evaluator (doctor) will not know about the intervention. Worms will be provided to the caregiver and the patient in identical boxes with numbers one and two written on them.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shahid Sadoughi University of Medical Sciences, Yazd

Street address
Prof. Hessabi Ave.

City
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Province
Yazd

Postal code
8916978477

Approval date
2020-03-10, 1398/12/20

Ethics committee reference number
IR.SSU.MEDICINE.REC.1401.073

Health conditions studied

1

Description of health condition studied
Bacterial vulvovaginitis (Trichomonas vaginalis)

ICD-10 code
A59.01

ICD-10 code description
Trichomonal vulvovaginitis

Primary outcomes

1

Description
Complaints and clinical observations

Timepoint
Evaluation of complaints and clinical observations on days 1, 3 and 7 days after starting the use of thymol vaginal cream.

Method of measurement
Likert scale

Secondary outcomes

1

Description
Clinical observations and complaints

Timepoint
At the beginning of the study and after days 1, 3 and 7 days after starting to use the vaginal cream

Method of measurement
Likert scale

Intervention groups

1

Description
Intervention group: patients with bacterial vulvovaginitis treated with topical thymol vaginal cream 5 mg, every night for up to one week.
Category
Treatment - Drugs

2

Description
Control group: Patients with bacterial vulvovaginitis treated with metronidazole 500 mg tablets twice a day for up to one week
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Yazd Reproductive Sciences Institute
Full name of responsible person
Dr. Leila Zanbag
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Sponsors / Funding sources

1

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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
Yazd 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
Yazd University of Medical Sciences
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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
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
There is no further information
When the data will become available and for how long
The access period starts 6 months after the results are published
To whom data/document is available
Researchers working in academic and scientific institutions
Under which criteria data/document could be used
There is no further information
From where data/document is obtainable
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What processes are involved for a request to access data/document
جزئیات خاصی مد نظر نمی باشد
Comments