

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

A Comparison of the Effects of Oral Ferula Capsul and Oral Metronidazole Pill on Terichomonas Vaginalis Infection Treatment

Protocol summary

Study aim

To Identify the effectiveness of Oral Ferula Capsul and Oral Metronidazole Pill on Terichomonas vaginalis infection Treatment

Design

This study is conducted on two parallel groups on 60 women in the intervention group 1 and 2. Metronidazole tablets are prescribed for one group and Ferula capsules are prescribed for another one. In order to keep the ethics of the study, samples should cooperate voluntarily and by random.

Settings and conduct

health tips and the way the medicine should be consumed are taught to both groups in DIC centers and Qa'im and Um al-Banin gynecologic clinics. One group should use 500-mg oral metronidazole tablets and the other should use 250-mg oral capsule twice a day for a period of 7 days. Then, within 2 to 7 days after the completion of the medication, if there is no menace, a laboratory examination of the treatment success is measured.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All Iranian women who are married and non-pregnant, who have sex with their spouse and who have clinical and laboratory symptoms of Trichomonas vaginalis infection, are not allergic to metronidazole and Appliance.

Intervention groups

500-mg Metronidazole tablets and 250-mg Ferula capsules are prepared from the angiogenesis and after getting consent letter and a full explanation of the therapeutic method for the intervention groups 1 and 2, metronidazole tablets or capsules are given and they are asked to consume them every 12 hours. Health tips and methods of using the medication are taught to both groups, and a 500 mg oral metronidazole tablet is given to one group and oral Ferula capsule will be given to the another one. Both groups should consume medicine the twice a day.

Main outcome variables

Negative result of vaginal mucus in wet smear considering Trichomoniasis parasite and the negative sign of trichomoniasis clinical symptoms

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190220042776N1**

Registration date: **2019-04-01, 1398/01/12**

Registration timing: **prospective**

Last update: **2019-04-01, 1398/01/12**

Update count: **0**

Registration date

2019-04-01, 1398/01/12

Registrant information

Name

Sara Bagherinasab

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3859 1511

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bagherinasabs961@mums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-09, 1398/01/20

Expected recruitment end date

2019-06-10, 1398/03/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparison of the Effects of Oral Ferula Capsul and Oral Metronidazole Pill on Terichomonas Vaginalis Infection Treatment

Public title

The Effects of Oral Metronidazole Pill on Trichomonas Vaginalis Infection Treatment

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Being Iranian To cooperate willingly Having at least the ability of reading and writing Being married Having sexual relationship with her spouse Not having Pelvic inflammatory disease (PID) She should use condom during the course of treatment Having no particular medical condition The total score for signs and symptoms of Trichomonas vaginalis is at least 1 in the examination and interview A wet specimen test being positive for Trichomoniasis Not having recurrent Trichomoniasis

Exclusion criteria:

Having sex without using condom during treatment There is no history of allergy to oral metronidazole tablets and Appliance Not using antibiotics or anti-parasites within two weeks Having abnormal uterine bleeding (AUB / DUB) Not using the treatment for one day or using twice a day Being pregnant

Age

No age limit

Gender

Female

Phase

2-3

Groups that have been masked*No information***Sample size**

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

Randomize easily and easily

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

To keep the ethics of the study, firstly, the written permission must be obtained from the Ferula group voluntarily so there is no possibility of blindness and semi-experimental study.

Secondary Ids

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

National Ethics Committee for Biomedical Research of Mashhad University of Medical Science

Street address

Ibn Sina/ faculty of Nursing and Midwifery

City

Mashhad

Province

Razavi Khorasan

Postal code

9137913199

Approval date

2019-03-05, 1397/12/14

Ethics committee reference number

IR.MUMS.NURSE.REC.1397.090

Health conditions studied**1****Description of health condition studied**

Trichomonas vaginalis

ICD-10 code

N77.1

ICD-10 code description

Vaginitis, vulvitis and vulvovaginitis in infectious and parasitic diseases classified elsewhere

Primary outcomes**1****Description**

Negative result of Vaginal mucus test smear test of woman with Trichomonas vaginal infection

Timepoint

2 and 7 days after the completion of the medication if it the person does not have period, otherwise if the sample experiences a monthly pattern after the end of the period

Method of measurement

Vaginal mucus wet smear test

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group1: Health Tips and Appropriate

medicine consumption (twice a day, for seven days every 12 hours) are taught. Oral pills 500 mg of metronidazole is prescribed. After the completion of the medication the negative smear test is needed if the samples are not experiencing Period. If the sample experiences a monthly pattern, the test is done after its end.

Category

Treatment - Drugs

2

Description

Intervention group2: The samples enter the group voluntarily. Health Tips and Appropriate medicine consumption (twice a day, for seven days every 12 hours) are taught. Oral pills 250mg of Ferula capsule is prescribed. After the completion of the medication the negative smear test is needed if the samples are not experiencing Period. If the sample experiences a monthly pattern, the test is done after its end.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

DIC center and Women's Clinic of Qa'im and Um Al-Benin Hospital

Full name of responsible person

Mahin Tafazoli

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Ibn Sina street - Faculty of Nursing and Midwifery

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Mashhad University of Medical Sciences

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?

Yes

Title of funding source

Mashhad 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

Mashhad University of Medical Sciences

Full name of responsible person

Sara Bagherinasab

Position

Master Student of Midwifery

Latest degree

Bachelor

Other areas of specialty/work

Health Promotion

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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

Person responsible for updating data**Contact****Name of organization / entity**

Mashhad University of Medical Sciences

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