

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Comparison of treatment with oral metronidazole vaginal cream Prangos ferulacea with oral metronidazole vaginal cream with placebo in the treatment of Trichomonas vaginalis infection in women

Protocol summary

Study aim

Determine the effect of Prangos ferulacea vaginal cream on accelerating the improvement of Trichomonas vaginalis.

Design

By target and target sampling, in 2018, 90 people will be randomly divided into two groups of 45 people.

Settings and conduct

was carried out in clinics affiliated with Lorestan University of Medical Sciences in women with diagnosis of trichomoniasis, based on patient complaints, clinical observations and wet and colored microscopic tests. Clinical observations and wet microscopic and staining tests are reviewed within 7 days of treatment. Data were analyzed using independent t-test, chi-square, exact Fisher, Mann-Whitney and McNemar with a significant level ($p < 0.05$).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Non-pregnant women 15 to 49 years old; Married non-lactating non-menopausal; Claimant from vaginal discharge; Regular menstrual cycles; Non-vaginitis; Non-use of vaginal or antibiotic drugs during the past 2 weeks; Non-participation in Other research studies over the past four weeks; no cervical dysfunctions; no chronic medical conditions and willing to participate in the present study (with informed written consent). Exit criteria: Unwillingness at each stage of the research, no drug use for one night; sexual intercourse; pregnancy; having menstrual bleeding and non-timely referral.

Intervention groups

Intervention group: Metronidazole tablets 250 mg, 500 mg orally twice daily (every 12 hours) with food for 7 days with Prangos ferulacea vaginal cream for 7 days. Control group: oral metronidazole 250 mg Grams, 500 mg twice daily (every 12 hours) with food for 7 days, together with placebo vaginal cream.

Main outcome variables

Direct vaginal observation (foamy yellowish discharge); Vaginal pH; Visum test; and microscopic observation of stained slides before and 7 days after treatment.

General information

Reason for update

Acronym

TVI

IRCT registration information

IRCT registration number: **IRCT20160423027534N2**

Registration date: **2019-01-04, 1397/10/14**

Registration timing: **retrospective**

Last update: **2019-01-04, 1397/10/14**

Update count: **0**

Registration date

2019-01-04, 1397/10/14

Registrant information

Name

Asieh Azadpourmotlagh

Name of organization / entity

(International Branch), Faculty of Nursing & Midwifery, Shahid Beheshti University of Medical Scienc

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-02-20, 1397/12/01
Expected recruitment end date
2019-03-21, 1398/01/01
Actual recruitment start date
2017-09-23, 1396/07/01
Actual recruitment end date
2018-09-23, 1397/07/01
Trial completion date
empty

Scientific title

Comparison of treatment with oral metronidazole vaginal cream Prangos ferulacea with oral metronidazole vaginal cream with placebo in the treatment of Trichomonas vaginalis infection in women

Public title

The effect of vaginal cream Prangos ferulacea Brghvnt Trichomonas vaginalis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Inclusion criteria: 15-49 year old married women Non pregnant Non breast feeding Non menopause Non smoker Willing to participate in the research Complaine with foamy yellow green discharge Not having vaginal infections Not having unusual vaginal bleeding during the treatment Not intercouring during the treatment Not using vaginal ointment,suppository or douching from two days before treatment Not having chronic diseases like heart or kidney problems, diabetes, arthoritis Not using broad-spectrum antibiotics, hormones, anticoagulant and immunosuppressive medicine Not having allergic to metronidazole or topical medications

Exclusion criteria:

Exclusion criteria: Unwilling to continue to participate in the reseach Not using vaginal ointment for two consecutive days Being allergic to metronidazole or Prangos ferulacea vaginal cream or intolerance to any forms of medicine Having vaginal infections (bacterial vaginosis and candidiasis) having intercourse during in the treatment become pregnant during treatment incomplete questionnaire

Age

From **15 years** old to **49 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Available (simple) based on the target. In this way, all patients who have conditions of entry to the study, are examined. The delivery of drugs to patients is such that, in a box, a number of cards matching them equally, the letters of the English alphabet "A A" and "B" correspond to the vaginal cream code of the placebo and Prangos ferulacea (the researcher does not know the worms' content), and Patients randomly select a card and deliver the medicine according to the letters on the card.

Blinding (investigator's opinion)

Triple blinded

Blinding description

This study is a randomized, triangular blind clinical trial. The diagnosis of Trichomonas slides be encoded and the patient's name is not written. At the stage of giving the patient, the Prangos ferulacea vaginal cream and placebo are marked with the English letters A and B, which are coded by the pharmacist. The researcher is unaware of its contents, and the patient will randomly choose one of the vaginal creams. In the referral stage after treatment, the slides are also examined by another researcher. And the professor of statistics is also unaware of the control and intervention group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

National Committee of Ethics in Biomedical Research

Street address

Faculty of Nursing & Midwifery, In front of Shahid Rajai Hospital, Niayesh Expressway, Valiasr St, District3, Tehran.

City

Tehran

Province

Tehran

Postal code

1985717443

Approval date

2018-10-02, 1397/07/10

Ethics committee reference number

IR.SBMU.REC.1397.018

Health conditions studied

1

Description of health condition studied

Trichomoniasis vaginit

ICD-10 code

A59.01

ICD-10 code description

Trichomonal vulvovaginitis

Primary outcomes

1

Description

1- Evaluation of vaginal secretions in terms of color, odor by direct observation. 2. Transient trichomoniasis (under microscope) in wet smear.

Timepoint

Before interference and 7 days after treatment

Method of measurement

At first, the secretions and symptoms will be examined with direct vision. Then, using sterile cotton swabs, a vaginal discharge was taken and a 10% potassium solution was prepared on a lavender discharge prepared with sterile cotton swabs. And immediately poured a drop of saline samples under a microscope with a magnification of 400 (× 40) was seen moving trophozoite information.

2

Description

Observe the wet slides with a microscope

Timepoint

Before interference and 7 days after treatment

Method of measurement

With sterile cotton swabs, a sample of the secretions of the side walls of the vagina was removed and immediately underneath the microscope with magnification (× 40). If trichomoniasis is present in wet pearl trophozoites, they are approved.

Secondary outcomes

1

Description

Trichomoniasis vaginitis

Timepoint

En Before the intervention, seven days after start treatment.

Method of measurement

Samples are discharge from the sample by using the pH meter Strip, and after wetting the pH Strip, the color will change, and if the pH of the vaginal discharge is between 6-5, a wet test is performed.

Intervention groups

1

Description

Intervention group: metronidazole 250 mg orally, 500 mg twice daily (every 12 hours) with food for 7 days with our Prangos ferulacea vaginal cream.

Category

Treatment - Drugs

2

Description

Control group: metronidazole 250 mg orally, 500 mg twice daily (every 12 hours) with food for 7 days with our placebo vaginal cream.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Health centers affiliated to Lorestan University of Medical Sciences(Khorramabad city)

Full name of responsible person

Asieh Azadpourmotlagh, Master of Midwifery

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti 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
Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Asieh Azadpourmotlagh
Position
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Master
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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