

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparing the effect of proplis vaginal gel on trichomonas ectocervicitis.

Protocol summary

Study aim

The aim of this study was to evaluate the effect of propolis vaginal gel on trichomonas ectocervicitis.

Design

The clinical trial was performed on 112 patients in two equal groups of intervention (A) and control (B). This study was single blinded and randomization based on simple method

Settings and conduct

The ethical aspects of the study were investigated and confirmed by the Research Ethics Committee Isfahan University of Medical Sciences, and the necessary permissions were obtained. Participants who had the inclusion criteria enrolled in this one-blind study and randomization was conducted in intervention(A) or control(B) groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Iranian nationality; age: 18-45 years old; being sexually active (be married); having one partner; not pregnant or lactating; not during menstruation period; positive wet smear in both of groups; gynecologist confirmation of diagnosis; not having a history of drug allergy; not having a history of using antibiotics or vaginal drugs for ectocervicitis treatment in last 1 months ago; not having a history of using hormonal and immunosuppressive drugs; not having a history of some diseases such as: chronic diabetes melitus, anemia, renal diseases, liver diseases, cardiovascular diseases and etc..; not having a history of pelvic surgery. Exclusion criteria: occurrence of any undesirable incidence; not referred for follow up visits; irregular used of drugs (two consecutive nights or three not-consecutive nights); using other antibiotic or palliative treatments; having sexual function without used of condom.

Intervention groups

Intervention group: this patient used the gel containing extract of propolis for 7 nights. The patient of control group and husband of both group used of metronidazol 500 mg tablet twice a day for 7 days.

Main outcome variables

Healing of trichomonas ectocervicitis.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20091219002889N10**

Registration date: **2019-12-22, 1398/10/01**

Registration timing: **registered_while_recruiting**

Last update: **2019-12-22, 1398/10/01**

Update count: **0**

Registration date

2019-12-22, 1398/10/01

Registrant information

Name

Mahboubeh Valiani

Name of organization / entity

Isfahan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-09-15, 1398/06/24

Expected recruitment end date

2020-01-14, 1398/10/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of proplis vaginal gel on trichomonas ectocervicitis.

Public title

Comparing the effect of proplis vaginal gel on trichomonas ectocervicitis in women referred to gynecologic clinics of Isfahan educational centers (2019).

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Iranian race. 18-45 years old. Be sexually active(married). Had one sexual partner. Not pregnant or lactating. Not during menstruation period. Positive wet smear in both groups. A gynecologist confirmation of diagnosis. Not having a history of drug allergy. Not having a history of using antibiotics or vaginal drugs for ectocervicitis treatment in last 1 months ago. Not having a history of using hormonal and immunosuppressive drugs. Not having a history of some diseases such as: chronic diabetes melitus, anemia, renal diseases, liver diseases, cardiovascular diseases and etc... Not having a history of pelvic surgery.

Exclusion criteria:

Not interested in participating in the study. Not referred for follow up visits. Irregular used of drugs (two consecutive nights or three not-consecutive nights). Used of other antibiotics. Used of other palliative treatment. Having sexual function without used of condom.

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **112**

Randomization (investigator's opinion)

Randomized

Randomization description

A randomized controlled trial was carried out. One group of women who refer to clinics on the odd days. (Group A); the other group (Group B) refer to clinics on even-number days.

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 Isfahan University of Medical Sciences

Street address

Azadi Blvd., Hezar jerib Ave., milad dorm.

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Postal code

81746-73461

Approval date

2019-09-01, 1398/06/10

Ethics committee reference number

IR.MUI.REC.1398.001

Health conditions studied

1

Description of health condition studied

exocervicitis

ICD-10 code

N77.1

ICD-10 code description

Vaginitis, vulvitis and vulvovaginitis in diseases classified elsewhere

Primary outcomes

1

Description

Healing of trichomonas ectocervicitis.

Timepoint

Pre intervention,1 and 2 weeks after intervention

Method of measurement

Self-made questionnaire.

Secondary outcomes

1

Description

Healing of trichomonas ectocervicitis.

Timepoint

Preintervention,1 and 2 weeks after intervention

Method of measurement

Self-made questionnaire.

Intervention groups

1

Description

Intervention group: if this patient had the inclusion

criteria, after submitting a description and obtaining informed consent, received a vaginal gel containing 7.5% of propolis extract that prepared by Salafchegan Pharmaceutical Company, with seven sterile packaged applicators and 14 metronidazole tablets 500 mg for used by their spouses. Patients used of vaginal gel(half of the applicator) every night before bed for seven nights. At the same time, the intervention group's spouses were treated with metronidazole 500 mg twice a day (every 12 hours) for seven days. Patients were advised to refrain from sexual intercourse during treatment and were given pamphlet-based health-nutrition recommendations.

Category

Treatment - Drugs

2

Description

Control group: if this patient had the inclusion criteria, after submitting a description and obtaining informed consent, receive 28 metronidazole 500 mg tablets for treatment of themselves and their spouses. The patients and their spouse used the drug twice a day (every 12 hours) for 7 days. Patients were advised to refrain from sexual intercourse during treatment and were given pamphlet-based health-nutrition recommendations.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Beheshti Hospital

Full name of responsible person

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

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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
Esfahan 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

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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