Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 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

Country
Iran (Islamic Republic of)

Phone
+98 31 3651 4640

Email address
valiani@nm.mui.ac.ir

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 gynocologic 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.

City
Isfahan

Province
Isfehan

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
exocervisitis

ICD-10 code
N77.1

ICD-10 code description
Vaginitis, vulvitis and vulvovaginitis in diseases classified elsewhere

Primary outcomes

1

Description
Healing of trichomonas ectocervisiti.

Timepoint
Pre intervention,1 and 2 weeks after intervention

Method of measurement
Self-made questionnaire.

Secondary outcomes

1

Description
Healing of trichomonas ectocervisitis.

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

Seyedeh Shadi Taghavian

Street address

Motahari Ave., Shahid Beheshti Ave.

City

Isfahan

Province

Isfehan

Postal code

8174673461

Phone

+98 31 3236 7001

Fax

Email

Beheshti@mui.ac.ir

Web page address

2

Recruitment center

Name of recruitment center

Al-zahra hospital

Full name of responsible person

Seyedeh Shadi Tghavian

Street address

Shohadaye soffe Ave.

City

Isfahan

Province

Isfehan

Postal code

8174675731

Phone

+98 31 1668 5555

Fax

Email

Alzahra@mui.ac.iA

Web page address

3

Recruitment center

Name of recruitment center

Amin hospital

Full name of responsible person

Seyedeh Shadi Taghavian

Street address

Ibn sina Ave.

City

Isfahan

Province

Isfehan

Postal code

7346181746

Phone

+98 31 3303 3400

Fax

Email

Amin@mui.ac.ir

Web page address

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Mahboubeh Valiani

Street address

Isfahan University of Medical Sciences, Hezar jerebAve., Azadi Blvd.

City

Isfahan

Province

Isfehan

Postal code

8174673461

Phone

+98 31 3668 2006

Email

jazb@mui.ac.ir

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

Person responsible for general inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Seyedeh Shadi Taghavian

Position
MSc Student midwifery

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

Street address
Isfhan

City
Isfhan

Province
Isfehan

Postal code
8174673461

Phone
0098316689801

Email
Taqavianshadi@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Mahboube Valiani

Position
Assistant Professor

Latest degree
Ph.D.

Other areas of specialty/work
Midwifery

Street address
Isfahan University of Medical Science, Hezar jereb Ave., azadi Blvd.

City
Isfahan

Province
Isfehan

Postal code
8199939438

Phone
+98 31 3792 2936

Email
valiani@nm.mui.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Esfahan University of Medical Sciences

Full name of responsible person
Seyedeh Shadi Taghavian

Position
MSc Student midwifery

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

Street address
Isfahan University of Medical Science, Hezar Jereb Ave., Azadi Blvd.

City
Isfahan

Province
Isfehan

Postal code
8173785737

Phone
+98 31 3792 3086

Email
Taqavianshadi@gmail.com

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