

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 2026

The evaluation of the antifungal effect of Royal jelly on vaginal candidiasis; clinical randomized trial

Protocol summary

Study aim

average candida culture in the first group, consists of 45 patients treated with royal jelly before and after treatment will compared to the second group, consists of 45 patients treated with clotrimazole.

Design

This study is an open labels clinical trial that on 90 patients. Patients shall be included in the study randomly in two groups of 45 patients receiving royal jelly and 45 people in the control group receiving clotrimazole vaginal cream in equal numbers. The patients in the group receiving the royal jelly supplement receive royal jelly at a dose of 1000 mg daily for 10 days after the approval of the positive test of vaginal culture. In the control group, patients receive clotrimazole. Blood samples shall be taken in all of patients in order to measure the indicators related to the study and to evaluate the response to the treatment in a routine manner

Settings and conduct

The trial will be conducted in all hospitals related to Iran University of medicine

Participants/Inclusion and exclusion criteria

Inclusion criteria: married women with age between 18 and 50 with regular cycle. Exclusion criteria: pregnancy and breastfeeding, infection disases, immune compromise patients, organ transplant, cancer, liver and kidney diseases, resistant to treatment fungal and bacterial infections.

Intervention groups

two groups of 45 patients receiving royal jelly and 45 people in the control group receiving clotrimazole vaginal cream

Main outcome variables

It will be shown if there exists a significant difference between average candida culture in two group of patients treated with royal jelly or clotrimazole?

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220210053988N1**

Registration date: **2023-01-17, 1401/10/27**

Registration timing: **retrospective**

Last update: **2023-01-17, 1401/10/27**

Update count: **0**

Registration date

2023-01-17, 1401/10/27

Registrant information

Name

Maryam Ramazanichaleshtori

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6691 0602

Email address

dr.m.ramazani.m@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-03-21, 1400/01/01

Expected recruitment end date

2022-03-21, 1401/01/01

Actual recruitment start date

2021-03-21, 1400/01/01

Actual recruitment end date

2022-03-21, 1401/01/01

Trial completion date

2022-03-21, 1401/01/01

Scientific title

The evaluation of the antifungal effect of Royal jelly on vaginal candidiasis; clinical randomized trial

Public title

The antifungal effect of Royal jelly on vaginal candidiasis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Married women Age between 18-50 vaginal infection sign and symptoms

Exclusion criteria:

Pregnancy and breastfeeding immune compromise patients organ transplantation cancer renal and liver disease resistant treatment bacterial and fungal infections

Age

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

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

More than 1 sample in each individual

Number of samples in each individual: **2**

average of candidias culture before and after treatment

Actual sample size reached: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done with random allocation rule. We take 90 peaces of similar papers, on 45 cases wrote clotrimazole and on 45 cases wrote Royal Jelly. Mix them and put them in a bag and chose without constrained each time one case and order a list with output. Based on this list we know what kind of drug achieves the next patient.

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

IR.IUMS.FMD.REC.1399.865

Street address

Iran University of medical sciences

City

Tehran

Province

Tehran

Postal code

۱۴۴۹۶۱۴۵۳۵

Approval date

2021-03-07, 1399/12/17

Ethics committee reference number

IR.IUMS.FMD.REC.1399.865

Health conditions studied

1

Description of health condition studied

vaginal candidiasis

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

the average candida culture

Timepoint

From patients with vaginal signs we make the first culture test and set to lab. After the approval of the positive test of vaginal culture, the patients in the group receiving the royal jelly supplement, receive royal jelly at a dose of 1000 mg daily for 10 days. The second group that receive clotrimazole (control group), patients receive clotrimazole for ten nights, each night one applicator. Then we make the second culture test for both groups. We compare the results for two groups.

Method of measurement

cultivation environment for candidia, speculum, swap

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: This group consists of 45 patients which take royal jelly 1000 mg per day for ten days. The royal jelly used in this study with name Tang Forte is produced under licence of Health aid company of England by Omid Parsa company (OPD Pharma) of Iran. In this group we make vaginal smear culture one time before treatment and one time after treatment.

Category

Treatment - Drugs

2

Description

Control group: This group consists of 45 patients which

take clotrimazol in normal dose(one applicator each day) for ten days. In this group we make vaginal smear culture one time before treatment and one time after treatment too.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Hazrat Rasool Akram Hospital

Full name of responsible person

Lida Sojoody

Street address

Niayesh Street

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6435 1000

Email

Rasoolhospital@iums.ac.ir

Web page address

<https://hrmc.iums.ac.ir/>

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Dr. Hossein Keivani

Street address

Hemmat Highway

City

Tehran

Province

Tehran

Postal code

1449614535

Phone

+98 21 8670 1000

Email

info@iums.ac.ir

Web page address

<https://en.iums.ac.ir/>

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

No

Title of funding source

Iran 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**

Iran University of Medical Sciences

Full name of responsible person

Maryam Ramazanichaleshtori

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Kooye Asatid-A19-Isfahan University Of Technology

City

Isfahan

Province

Isfahan

Postal code

8415683111

Phone

+98 31 3391 3183

Email

dr.m.ramazani.m@gmail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Iran University of Medical Sciences

Full name of responsible person

Maryam Ramazanichaleshtori

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Kooye Asatid- A19-Isfahan University Of Technology

City

Isfahan

Province

Isfahan

Postal code

8415683111

Phone

+98 31 3391 3183

Email

m.dr.ramazani.m@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Maryam Ramazanichaleshtori

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

Street address

Kooye Asatid-A19-Isfahan University Of Technology

City

Isfahan

Province

Isfahan

Postal code

8415683111

Phone

+98 31 3391 3183

Email

dr.m.ramazani.m@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Questionnaire are available

When the data will become available and for how long

April 2023

To whom data/document is available

specialist and researchers of gynecology

Under which criteria data/document could be used

using for treatment or more investigations

From where data/document is obtainable

by email

What processes are involved for a request to access data/document

one week after receive email

Comments