

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Randomize comparison of Vaginal suppository containing zhumeria majdae essential oil with vaginal clotrimazole versus placebo vaginal suppository with vaginal clotrimazole for vulvovaginal candidiasis treatment

Protocol summary

Study aim

Randomize comparison of vaginal suppository containing Zhumeria majdae essential oil with vaginal Clotrimazole versus placebo vaginal suppository with vaginal Clotrimazole for vulvovaginal candidiasis treatment

Design

This study is a single blind randomized parallel clinical trial

Settings and conduct

This study will perform in gharazi medical Clinic in malayer

Participants/Inclusion and exclusion criteria

Inclusion criterias : Women aged 18 to 50 years, married, lack of sensitivity to Zhumeria majdae, lack of sensitivity to Clotrimazole, signature of consent form to participate in the study, Diagnosis of vaginal candidiasis infection
Exclusion criterias : Pregnancy and lactation, Menopause, Underlying diseases, Forgetting a dose or more, Patient unwillingness to continue treatment, Menstruation during the study, Abnormal uterine bleeding, Sensitivity to Zhumeria majdae, Sensitivity to clotrimazole

Intervention groups

1) Zhumeria majdae suppository 2)placebo suppository

Main outcome variables

1) Symptoms of candidal vaginitis (including: itching, burning, vaginal redness, inflammation, vaginal discharge) 2) Symptoms of candidal vaginitis (including: vaginal erythema, white cheesy discharge and inflammation) 3) Possible side effects of drugs in both groups
Therapies are compared

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150706023084N12**

Registration date: **2021-10-22, 1400/07/30**

Registration timing: **registered_while_recruiting**

Last update: **2021-10-22, 1400/07/30**

Update count: **0**

Registration date

2021-10-22, 1400/07/30

Registrant information

Name

MARYAM SHIEHMORTEZA

Name of organization / entity

AZAD UNIVERSITY PHARMACEUTICAL SCIENCES

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-10-05, 1400/07/13

Expected recruitment end date

2021-11-11, 1400/08/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Randomize comparison of Vaginal suppository containing

zhumeria majdae essential oil with vaginal clotrimazole versus placebo vaginal suppository with vaginal clotrimazole for vulvovaginal candidiasis treatment		Name of ethics committee Islamic Azad University of Medical Sciences, Tehran, Pharmacy and Pharmaceutical Sciences branches	
Public title Randomize comparison of Vaginal suppository containing zhumeria majdae essential oil with vaginal clotrimazole versus placebo vaginal suppository with vaginal clotrimazole for vulvovaginal candidiasis treatment		Street address Islamic azad University of Medical Sciences , Pharmacy and Pharmaceutical Sciences Branch , Yakhchal St., Gholhak, Dr. Shariati St. Tehran	
Purpose Treatment		City Tehran	
Inclusion/Exclusion criteria Inclusion criteria: women aged 18 to 50 years Married lack of sensitivity to the plant compounds of Zhumeria majdae lack of sensitivity to clotrimazole signature the consent form to participate in the study Exclusion criteria: pregnancy and lactation menopause underlying diseases forgetting a dose or more patient unwillingness to continue treatment menstruation during the study abnormal uterine bleeding sensitivity to Zhumeria majdae sensitivity to clotrimazole		Province Tehran	
		Postal code 1941933111	
		Approval date 2020-10-13, 1399/07/22	
		Ethics committee reference number IR.IAU.PS.REC.1399.168	
		Health conditions studied	
		<u>1</u>	
		Description of health condition studied candidiasis vulvovaginit	
		ICD-10 code N77.1	
		ICD-10 code description Vaginitis, vulvitis and vulvovaginitis in diseases classified elsewhere	
Age From 18 years old to 50 years old		Primary outcomes	
Gender Female		<u>1</u>	
Phase 1		Description itching	
Groups that have been masked • Participant • Care provider • Data analyser		Timepoint Start of study - 7 days after the start of the study	
Sample size Target sample size: 60		Method of measurement Questionnaire -Complete a checklist to evaluate the symptoms of candidal vaginitis and then compare the frequency of symptoms of candidal vaginitis within and between the two treatment groups.	
Randomization (investigator's opinion) N/A		<u>2</u>	
Randomization description		Description discharge	
Blinding (investigator's opinion) Single blinded		Timepoint Start of study - 7 days after the start of the study	
Blinding description Vaginal suppositories of Zhumeria majdae and placebo were made by the researcher and placed in aluminum foils individually, and everyone except the researcher was unaware of the drug composition.		Method of measurement Questionnaire	
Placebo Used		<u>3</u>	
Assignment Parallel		Description inflammation	
Other design features		Timepoint Start of study - 7 days after the start of the study	
Secondary Ids empty		Method of measurement Questionnaire	
Ethics committees		<u>1</u>	
<u>1</u>		Ethics committee	

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: It consists of 30 people, each of whom receives a 2-gram vaginal suppository containing 0.1 cc of *Zhumeria maidae* essential oil along with clotrimazole suppository every night for seven nights. Made in Tehran. Participants will be explained how to use the drug at the beginning of the study

Category

Treatment - Drugs

2

Description

Control group: It consists of 30 people, each of whom receives a 2-gram placebo suppository with clotrimazole suppository every night for seven nights. The user will be explained at the beginning of the study how to use the drug.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Gharazi Clinic in Malayer

Full name of responsible person

Sepideh Kermani

Street address

Shokoofeh Alley, Nobahar St., Sepah Square

City

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6571945546

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Email

drskermani43@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Islamic Azad University

Full name of responsible person

Dr Farshad Hashemian

Street address

Islamic azad university of medical science, Khaghani

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Province

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Email

info@iau.ac.ir

Web page address

http://iaups.iautmu.ac.ir/fa

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Islamic Azad University

Proportion provided by this source

100

Public or private sector

Private

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

Islamic Azad University

Full name of responsible person

Sepideh Kermani

Position

Pharmacy student

Latest degree

A Level or less

Other areas of specialty/work

Medical Pharmacy

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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

Not applicable

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

Islamic Azad University

Full name of responsible person

Dr Maryam Shiee Morteza

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Medical Pharmacy