

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

The effect of Rose extract (*Rosa damascena*) on sesame oil base in women with cervicitis

Protocol summary

Study aim

The effect of vaginal product of roses on clinical symptoms in patients with cervicitis and If the effect of rosemary oil on cervicitis treatment is proven by this plan, it may be possible to formulate and prepare a vaginal drug for this traditional medicine product and introduce a new drug for the treatment of patients.

Design

Patients will be randomly assigned to either of the two groups of rosacea oil and standard drug treatment for cervicitis.

Settings and conduct

This study will be a clinical trial on 52 patients with Cervicitis who referred to the Women's Clinic of Shahid Sadoughi Hospital of Yazd. In the first group, patients will be treated with rose oil for two weeks, 3cc per night of drug content, and in the second group, standard drug therapy will be used in the treatment of cervicitis. The patient will return for two weeks to complete the treatment to reassess and evaluate the therapeutic response. If the patient does not recover, the gynecologist will receive routine medical treatment.

Participants/Inclusion and exclusion criteria

52 married women aged 17-55 years will be included in the study with diagnosis of cervicitis and if they are not pregnant and breastfeeding, with no history of cervical polyps and pelvic surgery and no concurrent use of herbal or chemical medication after obtaining informed consent.

Intervention groups

The first group of patients treated with rose oil The second group is standard drug use in the treatment of cervicitis

Main outcome variables

Irritation;Itching;Discharge;Pain after intercourse;Post intercourse bleeding

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190810044500N1**

Registration date: **2020-03-29, 1399/01/10**

Registration timing: **registered_while_recruiting**

Last update: **2020-03-29, 1399/01/10**

Update count: **0**

Registration date

2020-03-29, 1399/01/10

Registrant information

Name

Fatemeh Saghafi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3820 3419

Email address

f.saghafi@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-16, 1398/09/25

Expected recruitment end date

2020-08-15, 1399/05/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Rose extract (Rosa damascena) on sesame oil base in women with cervicitis		2019-11-11, 1398/08/20
Public title "The effect of Rose oil in women with cervicitis"		Ethics committee reference number IR.SSU.MEDICINE.REC.1398.195
Purpose Treatment		Health conditions studied
Inclusion/Exclusion criteria Inclusion criteria: Women 17-55 years with a diagnosis of cervicit based on the opinion of a gynecologist Consent to participate in the study Exclusion criteria: Non-pregnancy and lactation No history of cervical polyps and pelvic surgery No simultaneous use of herbal or other chemicals		1 Description of health condition studied Cervicit ICD-10 code N72 ICD-10 code description Inflammatory disease of cervix uteri
Age From 17 years old to 55 years old		Primary outcomes
Gender Female		1 Description Mean of Wound size Timepoint Before the intervention, after completion of the intervention Method of measurement Clinical examination
Phase 2		2 Description Mean of Wound depth Timepoint Before the intervention, after completion of the intervention Method of measurement Clinical examination
Groups that have been masked No information		Secondary outcomes
Sample size Target sample size: 52		1 Description The amount of discharge Timepoint Before intervention, after intervention Method of measurement Clinical examination and patient based on VAS criteria
Randomization (investigator's opinion) N/A		2 Description Tenderness Timepoint Before intervention, after intervention Method of measurement Clinical examination
Randomization description		3 Description irritation Timepoint
Blinding (investigator's opinion) Not blinded		
Blinding description		
Placebo Not used		
Assignment Single		
Other design features The composition of the studied drug has been extracted from authentic sources of Iranian traditional medicine.		
Secondary Ids empty		
Ethics committees		
1 Ethics committee Name of ethics committee insitutional research Ethics Committee school of medicine - shahid sadoughi university of medical sc Street address yazd- yazd-shohaday gomnam blvd-shahid sadoughi university of medical sciences City yazd Province Yazd Postal code 8915173143 Approval date		

Before intervention, after intervention
Method of measurement
VAS criterion

4

Description
Itching
Timepoint
Before intervention, after intervention
Method of measurement
VAS criterion

5

Description
Pain after intercourse
Timepoint
Before intervention, after intervention
Method of measurement
Yes - no

6

Description
Post intercourse bleeding
Timepoint
Before intervention, after intervention
Method of measurement
Yes - no

Intervention groups

1

Description
Intervention group: Patients treated with rose oil for two weeks will be given 3 ml of drug content every night.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Gynecology clinic of Shahid Sadoughi Hospital, Yazd
Full name of responsible person
Zahra Dosthosseini
Street address
No. 59, Farhad Alley, Navab Safavi Boulevard
City
Yazd
Province
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8918836986
Phone
+98 35 3528 0048
Email
doost.fatemeh74@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Masoud Mirzaei
Street address
Bahonar Ave
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Postal code
9856783459
Phone
+98 35 3146 2056
Email
mmirzaei@ssu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yazd University of Medical Sciences
Proportion provided by this source
1
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
Other

Person responsible for general inquiries

Contact
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Zahra Dosthosseini
Position
University student
Latest degree
Medical doctor
Other areas of specialty/work
Medical Pharmacy
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No. 59, Farhad Alley , Safavi Boulevard
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Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Fateme saghafi

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

Zahra Dosthosseini

Position

University student

Latest degree

Medical doctor

Other areas of specialty/work

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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