Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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)

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+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

Public title
''The effect of Rose oil in women with cervicitis''
Purpose
Treatment
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
Age
From **17 years** old to **55 years** old
Gender
Female

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **52**
Randomization (investigator's opinion)
N/A
Randomization description
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
2019-11-11, 1398/08/20
Ethics committee reference number
IR.SSU.MEDICINE.REC.1398.195

Health conditions studied

1

Description of health condition studied
Cervicit
ICD-10 code
N72
ICD-10 code description
Inflammatory disease of cervix uteri

Primary outcomes

1

Description
Mean of Wound size
Timepoint
Before the intervention, after completion of the intervention
Method of measurement
Clinical examination

2

Description
Mean of Wound depth
Timepoint
Before the intervention, after completion of the intervention
Method of measurement
Clinical examination

Secondary outcomes

1

Description
The amount of discharge
Timepoint
Before intervention, after intervention
Method of measurement
Clinical examination and patient based on VAS criteria

2

Description
Tenderness
Timepoint
Before intervention, after intervention
Method of measurement
Clinical examination

3

Description
irritation
Timepoint

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

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8918836986

Phone

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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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9856783459

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+98 35 3146 2056

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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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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

Medical Pharmacy

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Person responsible for updating data

Contact

Name of organization / entity

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Full name of responsible person

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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