

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jun 2026

Comparison of the Effects of Vaginal Honey Jelly with Vaginal Lubricant Gel on Atrophic vaginitis symptoms and Quality of life in Post menopausal Women with Endometrial cancer

Protocol summary

Study aim

Comparison of the Effects of Vaginal Honey Jelly with Vaginal Lubricant Gel on Atrophic vaginitis symptoms and Quality of life in Post menopausal Women with Endometrial cancer to improve life quality in women with endometrial cancer

Design

This study Will be a Single-blind randomized controlled clinical trial two arm parallel, that will be done on 64 postmenopausal women with endometrial cancer referred to Women clinics of KOSAR Hospital of Urmia. After accepting the study, they will be divided in two groups using vaginal lubricant jelly or vaginal Honey Gel, based on Even and Odd days.

Settings and conduct

The study will be done on 64 postmenopausal women with endometrial cancer referred to Women clinics of KOSAR Hospital of Urmia. After accepting the study, they will be divided in two groups containing 32 subjects; using vaginal lubricant jelly or vaginal Honey Gel, based on Even and Odd days. Data will be collected using two forms of questionnaire. The Menopause-specific Quality of Life (MENQOL) questionnaire and VSQ questionnaire. The questionnaires will be completed pre- and post-intervention period by a person who is not involved in to the study as a personal interview. Patients and all persons who collect data and analyze them will be unaware of the type of medication prescribed.

Participants/Inclusion and exclusion criteria

Inclusion criteria: At least 12 months of amenorrhea; Symptoms of atrophic vaginitis; History of endometrial cancer Exclusion criteria: Dissatisfaction to participate in the study; Allergy to Honey

Intervention groups

First group: Using Vaginal Honey Gel Second group: Using Vaginal Lubricant Jelly

Main outcome variables

Improvement of symptoms of atrophic vaginitis in women with endometrial cancer. Improvement of Life style in women with endometrial cancer. Improvement of vasomotor symptoms in women with endometrial cancer. Improvement of sexual complications in women with endometrial cancer.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180211038692N1**

Registration date: **2018-03-03, 1396/12/12**

Registration timing: **registered_while_recruiting**

Last update: **2018-03-03, 1396/12/12**

Update count: **0**

Registration date

2018-03-03, 1396/12/12

Registrant information

Name

Samira Mirzaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 41 3330 2171

Email address

samira.mirzaei.dr@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-08, 1396/11/19

Expected recruitment end date

2018-04-08, 1397/01/19
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the Effects of Vaginal Honey Jelly with Vaginal Lubricant Gel on Atrophic vaginitis symptoms and Quality of life in Post menopausal Women with Endometrial cancer

Public title
Effects of Vaginal Honey Gel in Endometrial Cancer

Purpose
Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

At least 12 months of amenorrhea Symptoms of vaginal atrophy History of Endometrial cancer

Exclusion criteria:

Dissatisfaction to participate in the study Allergy to honey

Age
No age limit

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size
Target sample size: **64**
Actual sample size reached: **60**

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description
After accepting to contribute in this clinical trial, women will be divided in 2 groups based on even and odd days, using vaginal lubricant jelly or vaginal honey gel. Patients will be unaware of the type of medication prescribed. The questionnaire will be completed pre and post-intervention period by a person who is not involved in to the study as personal interview. Data collection and analyzes will be done by a person who is not involved in to the study.

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Urmia University of Medical Science

Street address

Motahhari Hospital., Kashani Ave., Urmia., West Azarbayjan

City

Urmia

Province

West Azarbaijan

Postal code

5715615463

Approval date

2018-01-29, 1396/11/09

Ethics committee reference number

IR.UMSU.REC.1396.366

Health conditions studied

1

Description of health condition studied

Atrophic vaginitis

ICD-10 code

N95.2

ICD-10 code description

Postmenopausal atrophic vaginitis

Primary outcomes

1

Description

The score of atrophic vaginitis

Timepoint

Filling the questionnaire at fist and 2 months after intervention

Method of measurement

MENQOL questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Using Vaginal Honey Gel

Category

Treatment - Drugs

2

Description

Intervention group: Using Vaginal Lubricant Jelly

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Motahhari Hospital

Full name of responsible person

Maryam Yusefi

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Motahhari Hospital., Kashani Ave., Urmia

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Fax**Email**

Samira.mirzaei.dr@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Iraj Mohebbi

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

Yes

Title of funding source

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Samira Mirzaei

Position

Resident of Gynecology

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available