Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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)
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+98 41 3330 2171
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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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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
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Person responsible for updating data

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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