Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 May 2026

The effect of vaginal Royal jelly and vaginal premarin on the quality of life of menopause women who referred to gynecology clinic of Hajar Hospital in Shahrekord

Protocol summary

Summary

This study was aimed to evaluate the effect of vaginal Royal jelly and vaginal premarin on the quality of life of menopause women who referred to gynecology clinic of Hajar Hospital in Shahrekord. This study was a clinical trial, double blind, single center, with random allocation. Physician and the patients were unaware about the medication type. The patients were allocated randomly in the study groups according to encoded sheets. The population of study was the eligible menopause women who referred to gynecology clinic of Hajar Hospital in Shahrekord. Inclusion criteria was diagnosis of menopause. The patients with sensitivity to premarin or honey products were excluded. Ninety menopause women were randomly allocated in premarin, Royal jelly, or lubricant groups (30 in each group). The intervention was conducted for three months. The quality of life and vaginal cytological assay were evaluated at the beginning and end of the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014112220043N1**
Registration date: **2015-01-03, 1393/10/13**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2015-01-03, 1393/10/13

Registrant information

Name

Fatemeh Seiedy

Name of organization / entity

Shahrekord University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 38133346692

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Recruitment status

Recruitment complete

Funding source

Shahrekord Medical University of Sciences

Expected recruitment start date

2013-09-23, 1392/07/01

Expected recruitment end date

2014-05-22, 1393/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of vaginal Royal jelly and vaginal premarin on the quality of life of menopause women who referred to gynecology clinic of Hajar Hospital in Shahrekord

Public title

The effect of vaginal Royal jelly and vaginal premarin on the quality of life of menopause women who referred to gynecology clinic of Hajar Hospital in Shahrekord

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Menopausal women; aged between 50 to 65 years; married women; diagnosis of vaginal atrophy Exclusion criteria: Diabetes mellitus; history of endometrial cancer; history of breast cancer; cystocele;

hormone therapy; sensitivity to honey products or premarin

Age
From **50 years** old to **65 years** old

Gender
Female

Phase
1-2

Groups that have been masked
No information

Sample size
Target sample size: **90**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Shahrekord University of Medical Sciences

Street address
Shahrekord University of Medical Sciences, Kashani Street, Shahrekord

City
Shahrekord

Postal code

Approval date
2013-08-25, 1392/06/03

Ethics committee reference number
92-3-7

Health conditions studied

1

Description of health condition studied
Menopause

ICD-10 code
N95.1

ICD-10 code description
Menopausal and female climacteric states

Primary outcomes

1

Description
Quality of life

Timepoint
At the beginning and end of the study

Method of measurement
Questionnaire

Secondary outcomes

1

Description
Vaginal atrophy

Timepoint
At the beginning and end of the study

Method of measurement
Pap-Smear test

Intervention groups

1

Description
Premarin group: The patients in this group were treated with vaginal premarin 0.625% for three months. Royal Jelly group: The patients in this group were treated with vaginal Royal jelly 15% in lubricant base for three months.

Category
Treatment - Drugs

2

Description
Lubricant group: The patients in this group were treated with vaginal lubricant gel for three months.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Gynecology clinic of Shahrekord Hajar Hospital

Full name of responsible person
Dr Fatemeh Seiedy

Street address
Rahmatiee, Shahrekord University of Medical Sciences, Shahrekord

City
Shahrekord

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahrekord University of Medical Sciences

Full name of responsible person
Dr Mahmood Mobasheri

Street address
Shahrekord University of Medical Sciences, Kashani Street, Shahrekord

City
Shahrekord

Grant name

Grant code / Reference number

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

Title of funding source
Shahrekord University of Medical Sciences

Proportion provided by this source
100

Public or private sector
empty

Domestic or foreign origin
empty

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
empty

Person responsible for general inquiries

Contact

Name of organization / entity
Shahrekord University of Medical Sciences

Full name of responsible person
Dr Fatemeh Seiedy

Position
Resident of Obstetrics and Gynecology

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty