

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)

Phone

+98 38133346692

Email address

st_seyedi@skums.ac.ir

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