

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 2026

The effect of Citrus aurantium vaginal cream on vaginal atrophy in postmenopausal women

Protocol summary

Study aim

The effect of Citrus aurantium vaginal cream on vaginal atrophy in postmenopausal women

Design

Quasi-experimental one-group with pretest-posttest

Settings and conduct

Postmenopausal women with vaginal atrophy in Noor city receive Citrus aurantium vaginal cream for 4 weeks. Before the intervention and at the end of weeks 2 and 4, symptoms of vaginal atrophy are examined, vaginal discharge specimens are taken to check the degree of vaginal cell maturation, and vaginal pH is also checked by a pH meter.

Participants/Inclusion and exclusion criteria

Inclusion criteria: having amenorrhea for at least 12 months; age 45-65 years old; having sex with single spouse; normal Pap smear over the past 3 years; body mass index less than 30; complaining of vaginal atrophy symptoms (burning, itching, vaginal dryness and pain during intercourse); getting a score of ≥ 65 on the visual analogue scale (VAS); having at least one symptom of vaginal mucosa descriptive evaluation table symptoms; vaginal maturation value (VMV) < 50 ; vaginal pH value > 5 . Exclusion criteria: vaginal infection; excessive consumption of phytoestrogens such as soy during the 8 weeks prior to the study; use of hormone replacement therapy during the 8 weeks before the study; history of asthma and allergies to certain herbs or citrus fruits; use of vaginal drugs or any lubricant for at least 15 days prior to study; smoking, alcohol or any other drug; mammary mass; uterine bleeding or spotting; kidney disorders; hypertension; thyroid disorders; liver disorders; heart problems; psychological problems and epilepsy; use of monoamine oxidase drugs, antidepressants, blood pressure, thyroid medication, supplements and vitamins; prolapse of pelvic organs grade 3 or more.

Intervention groups

Citrus aurantium vaginal cream, one applicator every

night in first two weeks and one night in between in later two-weeks

Main outcome variables

Vaginal atrophy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200215046494N1**

Registration date: **2020-03-22, 1399/01/03**

Registration timing: **prospective**

Last update: **2020-03-22, 1399/01/03**

Update count: **0**

Registration date

2020-03-22, 1399/01/03

Registrant information

Name

Mahram Asgharpour

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 11 5217 3306

Email address

homeira_60@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-04-18, 1399/01/30

Expected recruitment end date

2020-09-20, 1399/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Citrus aurantium vaginal cream on vaginal atrophy in postmenopausal women

Public title

The effect of Citrus aurantium on vaginal atrophy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having amenorrhea for at least 12 months Age 45-65 years old Having sex with single spouse Normal Pap smear over the past 3 years Body mass index less than 30 Complaining of vaginal atrophy symptoms (vaginal burning, vaginal itching , Vaginal dryness and pain during intercourse) Getting a score of ≥ 65 on the visual analogue scale (VAS) Having at least one symptom of vaginal mucosa descriptive evaluation table symptoms pH value > 5 Vaginal maturation value (VMV) < 50

Exclusion criteria:

Vaginal infection or any other important genital tract disease (sexually transmitted diseases) Excessive consumption of phytoestrogens such as soy, red clover, fenugreek and vitex during the 8 weeks prior to the study Use of hormone replacement therapy during the 8 weeks before the study A history of asthma and allergies to certain herbs or citrus fruits Use of vaginal drugs or any lubricant for at least 15 days prior to study Smoking, alcohol or any other drug Mammary mass Uterine bleeding or spotting Kidney Disorders, Kidney Failure, Hypertension, Thyroid Disorders, Liver Disorders, Heart Problems, Psychological problems and epilepsy Use of monoamine oxidase drugs, antidepressants, Antihypertensive drugs, thyroid medication, supplements and vitamins Prolapse of pelvic organs grade 3 or More

Age

From **45 years** old to **65 years** old

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

N/A

Randomization description**Blinding (investigator's opinion)**

Not blinded

Blinding description**Placebo**

Not used

Assignment

Single

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Gonabad University of Medical Sciences

Street address

Asian Road Margin, Gonabad University of Medical Sciences

City

Gonabad

Province

Razavi Khorasan

Postal code

9691793718

Approval date

2020-01-14, 1398/10/24

Ethics committee reference number

IR.GMU.REC.1398.142

Health conditions studied**1****Description of health condition studied**

Vaginal atrophy

ICD-10 code

N95.2

ICD-10 code description

Postmenopausal atrophic vaginitis

Primary outcomes**1****Description**

Vaginal acidity

Timepoint

Before and 2 and 4 weeks after intervention

Method of measurement

pH strip

2**Description**

Vaginal maturation value

Timepoint

Before and 2 and 4 weeks after intervention

Method of measurement

Vaginal smear

3**Description**

Subjective symptoms of vaginal atrophy

Timepoint

Before and 2 and 4 weeks after intervention

Method of measurement

Visual Analogue Scale

4

Description

Vaginal physical examination

Timepoint

Before and 2 and 4 weeks after intervention

Method of measurement

Vaginal physical examination checklist

Secondary outcomes

1

Description

Quality of life

Timepoint

Before and 2 and 4 weeks after intervention

Method of measurement

Menopause quality of life questionnaire (MENQOL questionnaire)

Intervention groups

1

Description

Citrus aurantium vaginal cream 4%, one applicator every night for two weeks and then one night in between in later two-weeks

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Women's Clinic of Noor city

Full name of responsible person

Mahram asgharpour

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Gonabad University of Medical Sciences

Full name of responsible person

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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

Gonabad 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

Gonabad University of Medical Sciences

Full name of responsible person

Mahram Asgharpour

Position

Master student

Latest degree

Bachelor

Other areas of specialty/work

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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

Participant information is confidential

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