Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 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 Asgharpoor
Name of organization / entity
Country
Iran (Islamic Republic of)
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+98 11 5217 3306
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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 questionare)

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 asgharpoor

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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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 Asgharpoor

Position

Master student

Latest degree

Bachelor

Other areas of specialty/work

Midwifery

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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