Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of urtica dioica plant vaginal cream on vaginal atrophy and sexual quality of life in menopausal women

Protocol summary

Study aim
Determining the effect of urtica dioica plant vaginal cream on vaginal atrophy and sexual quality of life in menopausal women

Design
Clinical trial with control and placebo groups, with parallel groups, three-way blind, randomized, phase 3 on 102 patients. Www.randomization.com site will be used for randomization.

Settings and conduct
The present study will be performed as a three-group randomized clinical trial on 102 postmenopausal women referring to Gorgan health centers. Sampling will be available. If the score is at least one of the signs of the Vaginal Assessment Scale (VAS) 4 or higher, the research unit selection form for individuals will be completed. Then the person undergoes a gynecological examination and vaginal pH is determined. A sample of vaginal cells will also be taken and sent to a laboratory to determine the vaginal maturation value (VMV). If the vaginal PH is above 5 and the VMV is less than or equal to 55%, the person will be considered as one of the research units. each of the creams has a code that only a pharmacist consultant knows about. Persons will randomly receive one of the 5% nettle vaginal creams, conjugated estrogen and placebo at a dose of one gram every night for 8 weeks, the first 2 weeks every night and the next 6 weeks twice a week. Follow-up will be done 4 and 8 weeks after the study.

Participants/Inclusion and exclusion criteria
Iranian and resident of gorgan; Married and sexually active in the past 6 months; Normal menopause; Age 45-60; Normal pap smear; Diagnosis of vaginal atrophy

Intervention groups
The intervention group will receive 5% urtica dioica plant vaginal cream and the control group will receive conjugated estrogen vaginal cream for 8 weeks, the first 2 weeks every night and the next 6 weeks twice a week.

Main outcome variables
Vaginal assessment scale (VAS); vaginal PH; Vaginal maturation index (VMI); vaginal maturation value (VMV)

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210216050382N1**
Registration date: **2021-02-25, 1399/12/07**
Registration timing: **prospective**

Last update: **2021-02-25, 1399/12/07**
Update count: **0**

Registration date
2021-02-25, 1399/12/07

Registrant information

Name
nahid nazari

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-05-22, 1400/03/01

Expected recruitment end date
2021-11-22, 1400/09/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of urtica dioica plant vaginal cream on vaginal atrophy and sexual quality of life in menopausal women

Public title
The effect of urtica dioica on vaginal atrophy

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
Iranian and resident of gorgan Satisfaction to participate in the study Literacy for reading and writing Married and sexually active in the past 6 months Normal menopause Age 45-60 Normal pap smear Diagnosis of vaginal atrophy (score of 4 or more on the vaginal atrophy questionnaire and vaginal PH greater than 5 and VMV equal to or less than 55)

Exclusion criteria:
Use of phytoestrogens (soy, flaxseed, red clover, fennel, nettle) one month before the start of the study Hormone therapy for 6 months before the start of the study Abnormal vaginal bleeding (spotting, pink or brown discharge, or obvious bleeding) Specific medical diseases (history of ovarian, breast and endometrial cancer - cardiovascular disease - history of thromboembolism or thrombophlebitis - history of coagulation diseases - history of ischemic stroke - migraine headaches - seizures - uterine leiomyoma - endometriosis - hypertension - diabetes - hyperlipidemia- liver and gallbladder disease - chronic kidney disease - tobacco use history - genitourinary abnormalities (uterine unicorn, bicornuate, double and septate) Use of certain medications (hormonal medications - moisturizers and vaginal gels - antihypertensive drugs - diuretics - antidepressants - antipsychotics - lithium - antihistamines - barbiturates - narcotics - benzodiazepines - hallucinogens - amphetamine – cocaine- digoxin) Vaginal infections (candida-trichomonas-bacterial vaginosis-std-herpes) History of estrogen sensitivity (breast pain, breast tenderness and sensation, spotting, itching, burning, redness) History of nettle sensitivity

Age
From **45 years** old to **60 years** old

Gender
Female

Phase
3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **102**

Randomization (investigator's opinion)
Randomized

Randomization description
The allocation of postmenopausal women to three groups of urtica dioica vaginal cream, conjugated estrogen and placebo will be simple random with random sequence created by www.randomization.com. The random sequence created by the site is provided to the pharmacist consulting professor so that the creams are labeled with one of the codes A, B and C without informing the other members of the research team. After the entry of each person with the conditions of inclusion in the study, according to the above random sequence, one of the creams A, B and C will be delivered to him.

Blinding (investigator's opinion)
Triple blinded

Blinding description
Urtica dioica vaginal cream, placebo and conjugated estrogen will be poured into exactly the same tubes. The creams are similar in shape and color and only the pharmacist consulting professor will know the codes assigned to the creams.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Mashhad University of Medical Sciences-School of Nursing and Midwifery

Street address
School of Nursing and Midwifery, Ibn Sina St., Doctora Crossroads, Daneshgah Street

City
Mashhad

Province
Razavi Khorasan

Postal code
9137913199

Approval date
2021-02-09, 1399/11/21

Ethics committee reference number
IR.MUMS.NURSE.REC.1399.092

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
Mental symptoms of vaginal atrophy
Timepoint
Before the study, 4 and 8 weeks after the intervention
Method of measurement
Vaginal assessment scale

2

Description
Vaginal PH
Timepoint
Before the study, 4 and 8 weeks after the intervention
Method of measurement
PH-indicator strips

3

Description
Vaginal maturation index
Timepoint
Before the study, 4 and 8 weeks after the intervention
Method of measurement
Pathological examination

4

Description
Vaginal maturation value
Timepoint
Before the study, 4 and 8 weeks after the intervention
Method of measurement
Pathological examination

Secondary outcomes

1

Description
The sexual quality of life
Timepoint
Before the study, 4 and 8 weeks after the intervention
Method of measurement
The sexual quality of life female questionaire

Intervention groups

1

Description
Intervention group: Vaginal cream 5. urtica dioica plant made in the pharmacology department of medicinal plants of Mashhad University of Medical Sciences, for 8 weeks, the first 2 weeks every night and the next 6 weeks twice a week, 1 gram (Equivalent to 50 mg of extract) will be used every night. In clinical trials, a dose of 600 mg has been used for allergic rhinitis, and 600-1200 mg daily for 6-9 weeks for benign prostatic hyperplasia. The average oral lethal dose in rats was estimated to be more than 30 g / kg for aqueous leaf extract and 1.3 g / kg for roots.
Category
Treatment - Drugs

2

Description
Control group: Conjugated estrogen vaginal cream for 8 weeks, the first 2 weeks every night and the next 6 weeks twice a week, 1 gram per night will be used.
Category
Treatment - Drugs

3

Description
Control group: Placebo vaginal cream containing Farabi cream base made in the Department of Medicinal Plants Pharmacology of Mashhad University of Medical Sciences, for 8 weeks, the first 2 weeks every night and the next 6 weeks twice a week, 1 gram per night will be used.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Gorgan health centers
Full name of responsible person
Morteza Gholami
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Sponsors / Funding sources

1

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Name of organization / entity
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Full name of responsible person
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Web page address
https://nurse.mums.ac.ir/

Grant name

Grant code / Reference number

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

Title of funding source
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Nahid Nazari

Position
Student

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

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Assistant Professor

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Other areas of specialty/work
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

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