

Clinical Trial Protocol

Iranian Registry of Clinical Trials

03 Jun 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. Wwww.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

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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 questionnaire

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

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Sponsors / Funding sources

1

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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
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

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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