

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The comparative of Vagiheal Barij® vaginal gel with estromarin cream in vaginal atrophy

Protocol summary

Study aim

Comparison of the effect of Vagiheal Barij® vaginal gel with estromarin cream in vaginal atrophy

Design

Randomised, , parallel group trial with blinded outcome assessment in pathology . Randomisation was computerised with concealed randomisation sequence carried out at health centers

Settings and conduct

This study was conducted 70 menopause women who suffered from dyspareunia at health centers Arak university of medical sciences. Blindness and randomization will be done by numbered closed envelopes and block randomisation. VAS was used to record severity of dyspareunia, burning, itching dryness and cellular maturation index of vagina before and after intervention. The first Estromarin cream group received 2.5 gr cream to 3 weeks. After that counties it for 3 weeks after one-week rest. While the other group will give 2.5 gr to 7 nights then counties two times in weeks for two months. symptoms and signs of atrophic vaginitis will evaluate during 3 weeks, one month and two month after intervention by VAS (0-10). Finally, cellular maturation index of vagina will be assessed two months after intervention

Participants/Inclusion and exclusion criteria

Inclusion criteria: Having vaginitis atrophic, at least 2 years passing to menopause Exclusion criteria: The women who are contraindicated with estrogen therapy such as Hypertension drugs, diabetes, history of thrombophlebitis or embolism, antiepileptic drugs, breast cancer, ovaries .. heart disease, abnormal bleeding, severe headaches

Intervention groups

Intervention group 1 is patients with atrophic vaginitis who using Vagiheal Barij gel Intervention group 2 is patients with atrophic vaginitis who using Estromarin cream

Main outcome variables

Itching, burning, dyspareunia, itching, vaginal cell maturation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190910044736N1**

Registration date: **2019-12-04, 1398/09/13**

Registration timing: **prospective**

Last update: **2019-12-04, 1398/09/13**

Update count: **0**

Registration date

2019-12-04, 1398/09/13

Registrant information

Name

Katayon Vakilian

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 3417 3506

Email address

dr.kvakilian@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-20, 1398/12/01

Expected recruitment end date

2020-08-22, 1399/06/01

Actual recruitment start date

2020-03-20, 1399/01/01

Actual recruitment end date

2020-09-22, 1399/07/01

Trial completion date

2021-03-21, 1400/01/01

Scientific title

The comparative of Vagiheal Barij® vaginal gel with estromarin cream in vaginal atrophy

Public title

The comparative of Vagiheal Barij® vaginal gel with estromarin cream in vaginal atrophy

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Menopausal women with dyspareunia itching and pain during intercourse dryness in vagina No abnormal uterus bleeding No diabetes No hypertension No heart diseases No thyroid disease At least two years pasted of menopause

Exclusion criteria:

Do not obey protocol treatment

Age

From **15 years** old to **60 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **300**

Actual sample size reached: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

They were randomly divided into two groups of intervention 1 and 2 by a randomized block allocation method (quadruple AA, BB).The blocks will be provided by Excel software with Rand's formula and the four blocks will be placed in closed envelopes respectively prepared by EXCEL , and the patients will be placed in one of the blocks by opening it.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features

No

Secondary Ids

empty

Ethics committees**1****Ethics committee**

Name of ethics committee

Ethics committee of Arak University of Medical Sciences

Street address

Basij square,Peyambare Azam campus,Arak University of Medical Sciences

City

Arak

Province

Markazi

Postal code

3848176941

Approval date

2019-08-24, 1398/06/02

Ethics committee reference number

IR.ARAKMU.REC.1398.156

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

Post menopausal Vaginitis atrophic

ICD-10 code

N95.2

ICD-10 code description

Postmenopausal atrophic vaginitis

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

The mean of itching , burning ,dyspareunia and vaginal cell maturation base on Visual Analog Scale 0-10

Timepoint

Three weeks ,one and 2 months after treatment

Method of measurement

Visual Analog Scale 0-10

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group1: Vagiheal gel Barij (Barij essence company), using an applicator (2.5 gram in 7 night)as a first treatment then 2 times in weeks. until 2 months.There is at least 5 micrograms of 8-perinyl narangine and at least 1.2 micrograms of xanthemol per vaginal gel vaginal gel

Category

Treatment - Drugs

2**Description**

Intervention group2 : Estromarin cream group(Aboureiha company), using an applicator 2.5

gram in 21 days, then one week rest and continue for 21 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Health centers in Arak

Full name of responsible person

Katayon Vakilian

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Basij square, Peyambare Azam campus-Ark University of Medical Sciences, Arak, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Alireza Kamali

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Basij square, Peyambare Azam campus-Ark University of Medical Sciences, Arak, Iran

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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

Arak University of Medical Sciences

Proportion provided by this source

30

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

2

Sponsor

Name of organization / entity

Barij Essence

Full name of responsible person

Reza Bekhradi

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NO78, Marzadaran street

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drbekhradi@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Barij Essence

Proportion provided by this source

70

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Industry

Person responsible for general inquiries

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Katayon Vakilian

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Family Health

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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