

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

The comparison of Hyaluronic Acid Vaginal Suppository with Vitamin E in the Treatment of Atrophic Vaginitis in Menopausal Women

Protocol summary

Summary

Introduction: The aim of this study was to compare the effectiveness of the vaginal suppository of hyaluronic acid and vitamin E for the treatment of atrophic vaginitis. **Material and Method:** This randomized, double-blind, comparison study was carried out at East Ahvaz number one health center. Inclusion criteria include: Presenting symptom of vaginal atrophy, Superficial vaginal cells with 5% or less, Vaginal pH more than 5. Exclusion criteria include: Genital Bleeding of unknown Cause, The use of Sex Hormones within the 8 weeks preceding study. Forty postmenopausal women with symptoms of vaginal atrophy were randomized in two group to take vaginal suppositories of 5 mg hyaluronic acid sodium salt (n=20) or 1 mg vitamin E (n=20) for 8 weeks. The symptoms of vaginal atrophy were evaluated by a self-assessed 4-point scale of composite score was determined as, none, mild, moderate and severe. Vaginal pH and maturation value were measured and compared in both the groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201105026364N1**

Registration date: **2011-07-13, 1390/04/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-07-13, 1390/04/22

Registrant information

Name

Sara Ziagham

Name of organization / entity

Ahvaz Jundishapur University of Medical Science

Country

Iran (Islamic Republic of)

Phone

+98 61 1336 7543

Email address

ziagham.s@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Ahwaz University of Medical Sciences

Expected recruitment start date

2010-08-23, 1389/06/01

Expected recruitment end date

2011-01-16, 1389/10/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of Hyaluronic Acid Vaginal Suppository with Vitamin E in the Treatment of Atrophic Vaginitis in Menopausal Women

Public title

Non Hormonal Treatment of Vaginal Atrophy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Age between 45 to 65, Amenorrhea at less 12 month or have hormone test with FSH level more than 40 unit, Presence of normal pap smears, Presenting symptom of vaginal atrophy, Vaginal pH more than 5, Superficial vaginal cells with 5% or less, Have Sexual activity Exclusion criteria: Vaginal infection, Genital Abnormalities, The use of Sex Hormones within the 8

weeks preceding study, Genital Bleeding of unknown Cause, Use of Phytoestrogens such as Soy, Red clover, Fenugreek, Vitex within the last one Month

Age

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

Gender

Female

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee of Ahvaz Jundishapur University of Medical Science

Street address

Department of Research and Information Technology
University of Medical Sciences, Ahvaz Jondishapour,
Ground Floor, City University, Ahvaz

City

Ahvaz

Postal code

6135715794

Approval date

2010-09-23, 1389/07/01

Ethics committee reference number

u-89163

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

Symptoms of Vaginal Atrophy

Timepoint

Before intervention, Two weeks after the intervention,
Four weeks after intervention, Eight weeks after
intervention

Method of measurement

Composite Score of Vaginal Symptoms

Secondary outcomes

1

Description

Vaginal Superficial Cells

Timepoint

after intervention, Two months after intervention

Method of measurement

Vaginal Cells Maturation Index

2

Description

Vaginal pH

Timepoint

Before intervention, Two months after intervention

Method of measurement

pH Test

Intervention groups

1

Description

Hyaluronic Acid, Vaginal Suppositories of 5 mg single for
2 months

Category

Treatment - Drugs

2

Description

Vitamin E, Vaginal Suppositories of 1 mg single for 2
months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz East Number One Health Center

Full name of responsible person

Sara Ziagham

Street address

No. 34, Danesh Avenue, District 3. Bamonar, Ahvaz

City
Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Jondi Shapur Ahvaz
University of Medical Sciences

Full name of responsible person

Dr. Mostafa Fegghi

Street address

Jondi Shapur Ahvaz University of Medical Sciences,
opposite the central building, Vice Chancellor for
Research, Ahvaz University of Medical Sciences,
Ahvaz

City

Ahvaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Jondi Shapur Ahvaz
University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Ahvaz Jundishapur University of Medical Science

Full name of responsible person

Sara Ziagham

Position

Graduate Student

Other areas of specialty/work

Street address

Jondi Shapur Ahvaz University of Medical Sciences,
School of Nursing and Midwifery, a city college, Ahvaz

City

Ahvaz

Postal code

Phone

+98 61 1227 2990

Fax

Email

Ziagham.s@ajums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Ahvaz Jundishapur University of Medical Science

Full name of responsible person

Zahra Abbaspoor

Position

Master Science

Other areas of specialty/work

Street address

Jondi Shapur Ahvaz University of Medical Sciences,
School of Nursing and Midwifery, a city college, Ahvaz

City

Ahvaz

Postal code

6135715794

Phone

+98 61 1373 8394

Fax

Email

Abbaspoor_z762@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Ahvaz Jundishapur University of Medical Science

Full name of responsible person

Sara Ziagham

Position

Graduate Student

Other areas of specialty/work

Street address

Jondi Shapur Ahvaz University of Medical Sciences,
Ground Floor, Department of Research and
Technology University of Medical Sciences, Ahvaz
Jondishapour, a city college, Ahvaz

City

Ahvaz

Postal code

6135715794

Phone

+98 61133333477

Fax

+98 61 1336 1544

Email

www.ajums.ac.ir

Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report
empty
Analytic Code

empty
Data Dictionary
empty