Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jun 2026

The effect of Oxytocin Vaginal Gel on Vaginal Atrophy and Sexual Function in Post-menopausal Women

Protocol summary

Study aim
The effect of oxytocin vaginal gel on vaginal atrophy and sexual function in post-menopausal women

Design
In this study, 96 people (48 in each group) of postmenopausal women who have been inclusion criteria to study at will be examined Ahvaz East Health Center. Participants will be divided to groups of interventional and control the method randomized blocks with 4 block size.

Settings and conduct
This study is a double-blind, randomized controlled clinical trial that will be carried out in postmenopausal women referred to the Ahvaz East Health Center.In this study, Researcher and Participating will be unware of oxytocin gel or placebo.The medication and placebo will be placed in closed envelopes according to the randomized list and different codes by person outside the study then assigned to any patient that enter the study.

Participants/Inclusion and exclusion criteria
Inclusion criteria: ages between 40 to 60 years; Amenorrhea at least 12 month or have a hormonal test with FSH level more than 40 international units.
Exclusion criteria: Treatment with HRT or using sex hormones within 8 weeks before study; Uterine bleeding and spotting

Intervention groups
The intervention group receiving vaginal gel 400 IU oxytocin and a control group receiving placebo vaginal gel

Main outcome variables
vaginal atrophy; sexual function

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160602028220N2**
Registration date: **2018-02-09, 1396/11/20**
Registration timing: **prospective**

Last update: **2018-02-09, 1396/11/20**
Update count: **0**

Registration date
2018-02-09, 1396/11/20

Registrant information

Name
Ilnaz Zohrabi

Name of organization / entity
School of Nursing and Midwifery, Ahvaz Jundishapur Uninersity of Medical Science and Health Services

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2018-02-19, 1396/11/30

Expected recruitment end date
2018-07-22, 1397/04/31

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
The effect of Oxytocin Vaginal Gel on Vaginal Atrophy and Sexual Function in Post-menopausal Women

Public title
The effect of Oxytocin on Vaginal Atrophy and Sexual Function in Post-menopausal Women
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Have reading and writing skills Women aged 40-60 Passing for at least one year from the last menstruation or having a hormonal test with FSH of more than 40 international units The presence of vaginal atrophy Sexual performance score less than or equal to 26/5 Have sex and monogamy
Exclusion criteria:
vaginal infection Treatment with HRT or taking sex hormones during 8 weeks before study Any major disease genital Consuming Smoking, alcohol or any opiate Uterine bleeding and spotting Body mass index more than 30 Breast disease with unknown cause Use of vaginal drugs or any lubricant for at least 15 days before the study
Age
From **40 years** old to **60 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **96**
Randomization (investigator's opinion)
Randomized
Randomization description
Sampling will be done a non-probabilistic manner. The method of assigning medication and placebo to patients is randomized and randomized blocks with block size 4(using a random permutation table). A randomized list provide by a statistician. In this study, medication and placebo will be placed in the closed envelopes according to the randomized list and different codes by the person outside the study then assigned to any patient that enter the study. Medication and placebo are identical in appearance, packaging, color. The nature of the medication and placebo are apparenc after the analysis of the results.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, Researcher and Participating will be unware of oxytocin gel or placebo and the pharmacist will fill the oxytocin gel or placebo tubes. For this purpose, the medication and placebo will be placed in closed envelopes according to the randomized list and different codes by a person outside the study then assigned to any patient that enter the study. Medication and placebo are identical in appearance, packaging, color. The nature of the medication and the placebo will be appear after the analysis of the results.The will be explored about the purpuse of study to participants, but will be reminded them that identical and random their placement in each of the groups.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Ahvaz JundiShapur University of Medical Sciences and Health Services
Street address
Ahvaz Jundishapur University of Medical Science and Health Services, Golestan BLV, Ahvaz
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Ahvaz
Province
Khouzestan
Postal code
61357-15794
Approval date
2017-11-10, 1396/08/19
Ethics committee reference number
IR.AJUMS.REC.1396.720

Health conditions studied

1

Description of health condition studied
Vaginal atrophy and sexual function of postmenopausal women
ICD-10 code
N95.2
ICD-10 code description
Postmenopausal atrophic vaginitis

Primary outcomes

1

Description
symptoms of vaginal atrophy
Timepoint
At the beginning of the intervention and 14 and 56 days after the start of the intervention
Method of measurement
The combined questionnaire vaginal atrophy symptoms

2

Description
The percentage of the maturity of the cells of the vagina
Timepoint
before and after intervention
Method of measurement
Vaginal smears

3

Description
The acidity of the vagina
Timepoint
before and after intervention
Method of measurement
PH strip

Secondary outcomes

1

Description
sexual function
Timepoint
before and after intervention
Method of measurement
Female sexual function index questionnaire

Intervention groups

1

Description
Intervention group: after the preparation of the oxytocin powder, by the trusted pharmacist Ahvaz University of Medical Sciences will be made oxytocin vaginal gel 400 IU and will be given to the intervention group that used for vaginal each night for 8 weeks.They will be asking that they visit on days 14 and 56 after treatment to recheck and follow-up.That will be completed a checklist and FSFI questionnaire and the will be done clinical and laboratory investigation. Vaginal smear and measure the ph of the vagina will be conducted in just the first and last day of the visit and other assessments will be repeated each time the examination.
Category
Treatment - Surgery

2

Description
Control group: by the trusted pharmacist Ahwaz University of medical sciences will be made placebo vaginal gel 400 units from starch and other inert materials with the appearance is quite similar to the drug and appropriate conditions and that will be given to the intervention group that used for vaginal each night for 8 weeks.They will be asking that they visit on days 14 and 56 after treatment to recheck and follow-up.That will be completed a checklist and FSFI questionnaire and the will be done clinical and laboratory investigation. Vaginal smear and measure the ph of the vagina will be conducted in just the first and last day of the visit and other assessments will be repeated each time the examination.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Ahvaz Eeast Health Center
Full name of responsible person
Ilnaz Zohrabi
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz University of Medical Sciences
Full name of responsible person
Dr Mohamd Badavi
Street address
Ahvaz Jundishapur University of Medical Science and Health Services, Golestan BLV, Ahvaz
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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
Ahvaz 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
Ahvaz University of Medical Sciences
Full name of responsible person
Ilnaz Zohrabi
Position
Student Masters of Midwifery
Latest degree
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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