

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 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 unaware 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 University of Medical Science and Health Services

Country

Iran (Islamic Republic of)

Phone

+98 61 3373 8331

Email address

zohrabi.i@ajums.ac.ir

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 unaware 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 purpose 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

City

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 Ahvaz 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 East Health Center

Full name of responsible person

Ilmaz Zohrabi

Street address

Ahvaz East Health Center, Shahid Rastegari Street, Ahvaz

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Phone

+98 61 3373 8331

Fax

+98 61 3373 8333

Email

zohrabi.i@ajums.ac.ir

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

City

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Phone

+98 61 3373 8331

Fax

+98 61 3373 8333

Email

zohrabi.i@ajums.ac.ir

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

Khouzestan

Postal code

61357-15794

Phone

+98 61 3373 8331

Fax

+98 61 3373 8333

Email

zohrabi.i@ajums.ac.ir

Person responsible for updating data**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

Bachelor

Other areas of specialty/work

Midwifery

Street addressAhvaz Jundishapur University of Medical Science and
Health Services, Golestan BLV, Ahvaz**City**

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Phone

+98 61 3373 8331

Fax

+98 61 3373 8333

Email

zohrabi.i@ajums.ac.ir

Contact**Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

Ilnaz Zohrabi

Position

Student Masters of Midwifery

Latest degree

Master

Other areas of specialty/work

Midwifery

Street addressAhvaz Jundishapur University of Medical Science and
Health Services, Golestan BLV, Ahvaz**City**

Ahvaz

Province

Khouzestan

Postal code

61357-15794

Phone

+98 61 3373 8331

Fax

+98 61 3373 8333

Email

zohrabi.i@ajums.ac.ir

Person responsible for scientific 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

Bachelor

Other areas of specialty/work

Midwifery

Street addressAhvaz Jundishapur University of Medical Science and
Health Services, Golestan BLV, Ahvaz**City**

Ahvaz

Province**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