

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of the effect of 15ppm silver nanoparticles spray (Nivasha) and clotrimazole cream in the treatment of candida vaginitis

Protocol summary

Study aim

Comparison of the effect of 15ppm silver nanoparticles spray (Nivasha) with clotrimazole cream in the treatment of candida vaginitis

Design

Clinical trial with control group, with parallel groups, without blinding, randomized, on 100 , random allocation card was used for randomization.

Settings and conduct

100 women diagnosed with candida vaginitis in the gynecology clinic, randomly divided into two groups of intervention and control. In the intervention group, silver nanoparticles spray with applicator (Nivasha) with a concentration of 15 ppm for 10 consecutive days and once a day and 3 puffs each time and the control group of clotrimazole 1% vaginal cream is prescribed one applicator per night for 7 nights prescribed.

Participants/Inclusion and exclusion criteria

Women of childbearing age 15-49 years Married Consent to participate in the study Be literate Healthy women (without known immunosuppressive disease, hypertension, diabetes mellitus) Don't use of herbal and chemical drugs for vaginitis during recent 2 weeks Don't use of any vaginal cream 48 hours before onset of study No participation in another study at the same time as the present study Do not use antibiotics and corticosteroids for the past two weeks No report of allergy to Nivasha spray (containing silver) (if used previously) and clotrimazole (if used previously) Getting Candidate Vaginitis for the First Time Exclusion criteria: Menstruation, AUB, Antibiotic use

Intervention groups

Intervention group: Nivasha spray Control group: Vaginal cream clotrimazole

Main outcome variables

Recovery time, itching of the vulva and vagina, white vaginal discharge

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150624022896N2**

Registration date: **2022-01-03, 1400/10/13**

Registration timing: **registered_while_recruiting**

Last update: **2022-01-03, 1400/10/13**

Update count: **0**

Registration date

2022-01-03, 1400/10/13

Registrant information

Name

Maryam Kianpour

Name of organization / entity

School of Nursing and Midwifery, Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-12-22, 1400/10/01

Expected recruitment end date

2022-11-22, 1401/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of 15ppm silver nanoparticles spray (Nivasha) and clotrimazole cream in the treatment of candida vaginitis

Public title

Treatment of candida vaginitis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Women of childbearing age 15-49 years Married women Consent to participate in the study Be literate No pregnancy No breast feeding and menopause Having 2 symptoms of candida vaginitis (vaginal discharge, itching) Healthy women (without known immunosuppressive disease, hypertension, diabetes mellitus) Don't use of herbal and chemical drugs for vaginitis during recent 2 weeks No other vaginal infections such as trichomoniasis Don't use of any vaginal cream 48 hours before onset of study No participation in another study at the same time as the present study Do not use antibiotics and corticosteroids for the past two weeks No report of allergy to Nivasha spray (containing silver) (if used previously) and clotrimazole (if used previously) Getting Candida Vaginitis for the First Time

Exclusion criteria:

Menstruation at onset of study AUB Antibiotic use for systemic infections during study

Age

From **15 years** old to **49 years** old

Gender

Female

Phase

1

Groups that have been masked

No information

Sample size

Target sample size: **100**

More than 1 sample in each individual

Number of samples in each individual: **12**

In addition to the initial diagnosis, each sample is followed up for 10 consecutive days once at the end.

Randomization (investigator's opinion)

Randomized

Randomization description

First, 100 envelopes are prepared and named equally with codes 1 and 2. The codes are then placed inside the envelopes and sealed in the envelopes. All cards are placed in a box and patients are asked to take a card from the box containing the random allocation cards and deliver it to the questioner. Based on the card number, the women with card number 1, Nivasha spray and the women of card number 2, clotrimazole cream is delivered and how to use it is explained and the drug code is recorded in the questionnaire.

Blinding (investigator's opinion)

Not blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Research Ethics committees of vice chancellor in research- Affairs Medical University of Isfahan

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Hezar gerib Ave. Isfahan

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Postal code

8174673461

Approval date

2021-10-18, 1400/07/26

Ethics committee reference number

IR.mui.Research.Rec.1400.300

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

candida vaginitis

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Vulvar itching

Timepoint

Every day for 10 days

Method of measurement

Vaginal exam - Self report

2**Description**

Vulvar redness

Timepoint

Every 2 day for 10 days

Method of measurement

Vaginal exam - Self report

3**Description**

White cheese discharge

Timepoint

Every day for 10 days

Method of measurement

Vaginal exam - Self report

Secondary outcomes**1****Description**

Vulvar edema

Timepoint

Every day for 10 days

Method of measurement

Vaginal exam - self report

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

Intervention group: Nivasha spray containing 50 cc solution of silver nanoparticles with a concentration of 15 ppm for 10 consecutive days and once a day and 3 puffs each time is prescribed.

Category

Treatment - Drugs

2**Description**

Control group: Clotrimazole vaginal cream (1%) one applicator overnight for 7 consecutive nights in lithotomy position will be prescribed

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Isfahan University of Medical Sciences, Amir Hamzeh health Center

Full name of responsible person

Maryam Kianpour

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Nursing and Midwifery Research Center- Nursing and Midwifery faculty- Isfahan University of Medical Sciences- Hezar gerib Ave - Isfahan

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

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Grant name

240084

Grant code / Reference number

240084

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

No

Title of funding source

Isfahsn University of Mredical Scienes

Proportion provided by this source

45

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**

Esfahan University of Medical Sciences

Full name of responsible person

Maryam Kianpour

Position

Associate Professor

Latest degree

Ph.D.

Other areas of specialty/work

Gynecology and Obstetrics

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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

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Data is shared anonymously.

When the data will become available and for how long

2022

To whom data/document is available

Academic researchers - Pharmaceutical Industries

Under which criteria data/document could be used

Study outcome data are available.

From where data/document is obtainable

Dr Maryam Kianpour

What processes are involved for a request to access data/document

Obtaining a license from the Ethics Committee in Biomedical Research, Isfahan University of Medical Sciences and the Nursing and Midwifery Care Research Center

Comments