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 candidate 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: Mensturation, 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

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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 literrat 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:
Mensturation at onset of study AUB Antibiotice 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 commitees of vice chancellor in research- Affairs Medical University of Isfahan
Street address
Hezar gerib Ave. Isfahan
City
Isfahan
Province
Isfehan
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 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
Street address
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
Dr Yousof Gheisari
Street address
Vice chancellory for Research and Technology Isfahsn University of Mredical Scienes, Hezar gerib Ave. Isfahan
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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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Nursing and Midwifery Research Center- Nursing and Midwifery faculty- Isfahan University of Medical Sciences- Hezar gerib Ave - Isfahan
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Position
Associate Professor

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Gynecology and Obstetrics

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Person responsible for updating data

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Position
Associate profesor

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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