Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Investigation the effect of the Deo Drug anti fungal pan-gel on the external genital itching and burning following candidias vaginitis comparing to clotrimazole : a randomized contorted trial

Protocol summary

Summary

The current study is a prospective, randomized, controlled trial performed on women with Candida infection. This study will be conducted at the Ruin Tan Arash Hospital, Tehran, Iran. After written informed consent is obtained, patients will be allocated randomly to vaginal cream1% and Deo drug pan jell or control group using a random number sequence. Randomization will be done by using an online randomization program, with the use of permuted blocks with a random block size of 6 patients per block. Women in the intervention group will be used clotrimazol vaginal cream1% and Deo drug pan jell for external use. Women in the controlled group will be used clotrimazol vaginal cream1% as well as intervention group and for external use, they use clotrimazol topical cream. Duration of intervention in two groups will be 2 weeks. Clinical improvement of symptoms will be recorded in the form of clinical assessments and pelvic exams by gynecologist. As well as patient satisfaction of treatment, Dosage and duration of treatment will be recorded in the pre-designed forms.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016080829255N1**
Registration date: **2017-06-24, 1396/04/03**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2017-06-24, 1396/04/03

Registrant information

Name

Raziyeh Maasoumi

Name of organization / entity

Tehran University of Medical Sciences

Country

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Recruitment status

Recruitment complete

Funding source

Nictin Drug Industry

Expected recruitment start date

2017-05-22, 1396/03/01

Expected recruitment end date

2017-10-23, 1396/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation the effect of the Deo Drug anti fungal pan-gel on the external genital itching and burning following candidias vaginitis comparing to clotrimazole : a randomized contorted trial

Public title

The effect of Deoderag pan jell on external genital itching and burning in women with Candidiasis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria of this study is marital statues, confirmed clinical diagnosis of candida vulvovaginitis,

chief compliant of external symptoms and signs of vulvovaginitis, no usage of herbal medicine or any chemical antibiotics especially in the recent two weeks, no history of AUB, no usage of vaginal douching in the past 48 hours. Exclusion criteria of this study are overt diabet melitus, Immunosuppressive diseases,Vaginal drugs usage (as creams or gels) during the 4 weeks prior to study pregnancy, menopause, cervicitis, positive history of candidiasis more than 3 times per recent year, abnormal pap smear per recent year,having more than one sexual partner, and PID.

Age
From **18 years** old to **50 years** old

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **168**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single 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 the Tehran University of Medical Sciences

Street address
Tehran University of Medical Sciences, Ghods St

City
Tehran

Postal code

Approval date
2016-05-09, 1395/02/20

Ethics committee reference number
IR.TUMS.REC.1395.2757

Health conditions studied

1

Description of health condition studied
Candidiasis

ICD-10 code
N77.1*

ICD-10 code description
Vaginitis, vulvitis and vulvovaginitis in infectious and parasitic diseases classified elsewhere

Primary outcomes

1

Description
Clinical signs of candidia vaginitis

Timepoint
before and afert the intervention

Method of measurement
clinical pelvic exam observationform

2

Description
Clinical symptoms experienced by the patient

Timepoint
from the begining of the intervention untill finished it

Method of measurement
dailty patenit cheklist

Secondary outcomes

1

Description
recurrence of the vaginitis

Timepoint
4 weeks after the treatment

Method of measurement
recurrence evaluation form

2

Description
level of drug use satisfaction

Timepoint
after the intervention

Method of measurement
drug use satisfaction form

Intervention groups

1

Description
Women in the intervention group will be used clotrimazol vaginal cream1% for internal use and Deo drug pan jell for external use. Duration of intervention will be 2 weeks. The clotrimazol vaginal cream1% must be inserted into the vagina using the applicator provided, applied to the inside areas of the vagina. The Deo drug pan jell must be inserted into the vagina using the applicator provided, applied to the outside areas of the vagina. /

Category
Treatment - Drugs

2

Description

Women in the controlled group will be used clotrimazol vaginal cream1% as well as intervention group and for external use, they use clotrimazol topical cream. Duration of intervention will be 2 weeks. The clotrimazol vaginal cream1% must be inserted into the vagina using the applicator provided, applied to the inside areas of the vagina. The clotrimazol topical cream must be inserted into the vagina using the applicator provided, applied to the outside areas of the vagina.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Arash hospital

Full name of responsible person

Street address

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Nictin drug industry

Full name of responsible person

Ali Mohammad Eskandari

Street address

Mottahari st, Torkamanestan st, Ahmadyar avenue, P 21

City

Terhran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Nictin drug industry

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

Tehran University of Medical Sciences

Full name of responsible person

Dr. Raziyeh Maasoumi

Position

Pos.doc of Sexology, PhD of Reproductive Health, Assisstent Professor of Reproductive Health Departm

Other areas of specialty/work

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Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Dr. Raziyeh Maasoumi

Position

Post.doc of Sexology, PhD of Reproductive Health

Other areas of specialty/work

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Contact

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Other areas of specialty/work

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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