

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jun 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

Iran (Islamic Republic of)

##### Phone

+98 21 6105 4214

##### Email address

r\_masoumi@sina.tums.ac.ir

##### 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 complaint 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 diabetes mellitus, immunosuppressive diseases, vaginal drug 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 candida vaginitis

**Timepoint**

before and after the intervention

**Method of measurement**

clinical pelvic exam observation form

**2****Description**

Clinical symptoms experienced by the patient

**Timepoint**

from the beginning of the intervention until finished it

**Method of measurement**

daily patient checklist

**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 cream 1% for internal use and Deo drug pan jell for external use. Duration of intervention will be 2 weeks. The clotrimazol vaginal cream 1% 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,  
Assisitent Professor of Reproductive Health Departm

**Other areas of specialty/work**

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## Person responsible for scientific inquiries

### Contact

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## Person responsible for updating data

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assistant professor

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**Web page address**

## **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*