

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Comparison of the effect of Harpagophytum procumbens and topical Hydrocortisone in improving genital skin inflammation in patients with candidiasis

Protocol summary

Study aim

Using the most appropriate drug combination to improve genital skin inflammation in patients with candidal vaginitis by comparing the effect of harpagophytum procumbens extract and topical hydrocortisone in improving genital skin inflammation in these patients

Design

Clinical trial with control group, with parallel groups, triple blinded, randomized, phase 3 on 60 patients

Settings and conduct

Eligible people referring to Isfahan women's clinics in the years 1400 to 1401 are divided into two groups by using random assignment software. Patients' self-report sheet of their condition based on when the patient recovers from common complaints will be filled after taking medication at home and we will recommend them to refer again after treatment. In this study, the blind groups are patient, therapist, researcher, outcome evaluator, and data analyzer. Blinding is in the form of envelopes containing random codes for patients.

Participants/Inclusion and exclusion criteria

Being 15 to 50 years old, Being married, Examining the symptoms of acute candida vaginitis, Not taking broad-spectrum antibiotics in the last two weeks, Not using oral and vaginal medications related to the treatment of genital infections in the last two weeks, Lack of history of allergies to the ingredients in the creams, No trichomoniasis vaginitis

Intervention groups

Intervention is in the form of using a drug containing clotrimazole, idoquinol, aloe vera gel and Harpagophytum procumbens extract in one group and clotrimazole, idoquinol, aloe vera gel and hydrocortisone in the other group twice a day topically on the external genitalia and to It takes 7 days.

Main outcome variables

Measurement of burning, itching, inflammation and

redness of the genitalia

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210508051222N1**

Registration date: **2021-06-30, 1400/04/09**

Registration timing: **prospective**

Last update: **2021-06-30, 1400/04/09**

Update count: **0**

Registration date

2021-06-30, 1400/04/09

Registrant information

Name

reyhaneh daryabeigi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 31 3236 4028

Email address

tahereh.khalili@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-07-23, 1400/05/01

Expected recruitment end date

2023-03-20, 1401/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Harpagophytum procumbens and topical Hydrocortisone in improving genital skin inflammation in patients with candidiasis

Public title

Comparison of the effect of Harpagophytum procumbens and topical Hydrocortisone in improving genital skin inflammation in patients with candidiasis

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Having an age range of fifteen to fifty years Being married Signs and symptoms of candidate vaginitis in the interview

Exclusion criteria:

Use of broad-spectrum antibiotics in the last two weeks
Use of oral and vaginal medications related to the treatment of genital infections during the last two weeks
Any allergies to the drug compounds used in the research
Trichomonas vaginitis

Age

From **15 years** old to **50 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization is done with a simple random method and creating random values between zero and one in spss software. Values equal or less than 0.5 are assigned to group A and values greater than 0.5 are assigned to group B. Then, a person who was not a member of research team encodes 60 envelopes (based on the codes obtained in the randomization method) and determines the list of codes. New treatment or standard (conventional) treatment will be written in the envelope. One envelope will be given to each eligible patient according to their order of entry in the clinic to give to the specialist. The clinician will prescribe and make the necessary recommendations for each patient based on the grouping done. The researchers are blinded to patients group.

Blinding (investigator's opinion)

Triple blinded

Blinding description

The secretary introduces the patients to the clinician

based on the random allocated groups. Clinician provides treatment for each group according to their grouping. The researcher in collaboration with the clinician monitors patient's medication use. After collecting the data of the questionnaire that was completed by the patients, the data is given to the statistical specialist for analysis. Statistical specialist is blinded to patients group.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics Committee of Isfahan University of Medical Sciences

Street address

No. 119, Alborz Alley, 7th Alley, Hosseinzadeh Alley, Jihad St.

City

isfahan

Province

Isfahan

Postal code

8183886761

Approval date

2021-05-04, 1400/02/14

Ethics committee reference number

IR.MUI.MED.REC.1400.086

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

Candidal vulvovaginitis

ICD-10 code

B37.3

ICD-10 code description

Candidiasis of vulva and vagina

Primary outcomes**1****Description**

the amount of burning of external genitalia

Timepoint

Before the start of the study and 7 days after taking the drug

Method of measurement

5-points checklist

2

Description

the amount of itching of external genitalia

Timepoint

Before the start of the study and 7 days after taking the drug

Method of measurement

5-points checklist

3

Description

Amount of redness and swelling of the external genitalia

Timepoint

Before the start of the study and 7 days after taking the drug

Method of measurement

5-points checklist

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The weight of each ointment used in this group is 20 to 30 grams, which includes cold cream base made by Naghsh Jahan Company, Dr. Shahtalebi, and contains 20% of aloe vera gel extracted from the leaves, clotrimazole 2%, idoquinol 1% and 480 mg extract of Harpagophytum procumbens. Which is for external use and 2 times a day for a week.

Category

Treatment - Drugs

2

Description

Control group: Intervention group: The weight of each ointment used in this group is 20 to 30 grams, which includes cold cream base made by Naghsh Jahan Company, Dr. Shahtalebi, and contains 20% of aloe vera gel extracted from the leaves, clotrimazole 2%, idoquinol 1% and Hydrocortisone sodium succinate 1% . Which is for external use and 2 times a day for a week.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Al-Zahra Hospital

Full name of responsible person

Minoo Movahedi, Maryam Haji Hashemi, Tahereh Khalili, Reyhaneh Daryabeigi

Street address

No. 119, Alborz Alley, 7th Alley, Hosseinzadeh Alley, Jihad St.

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2

Recruitment center

Name of recruitment center

Amin Hospital

Full name of responsible person

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3

Recruitment center

Name of recruitment center

Beheshti Hospital

Full name of responsible person

Minoo Movahedi, Maryam Haji Hashemi, Tahereh Khalili, Reyhaneh Daryabeigi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Esfahan University of Medical Sciences

Full name of responsible person

Shaghayegh Hagh Jooi Javanmard

Street address

No. 119, Alborz Alley, 7th Alley, Hosseinzadeh Alley,
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Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Esfahan 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

Person responsible for general inquiries**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Reyhaneh Daryabeigi

Position

Intern

Latest degree

A Level or less

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Reyhaneh Daryabeigi

Position

Intern

Latest degree

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Other areas of specialty/work

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Person responsible for updating data**Contact****Name of organization / entity**

Esfahan University of Medical Sciences

Full name of responsible person

Reyhaneh Daryabeigi

Position

Intern

Latest degree

A Level or less

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

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