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
Being15 to 50 years old, Being married, Examining the symptoms of acute candidate 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, Jahad St.

City
isfahan

Province
Isfehan

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, Jahad 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
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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
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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
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Full name of responsible person
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Position
Intern
Latest degree
A Level or less
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for updating data

Contact

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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