Clinical Trial Protocol
Iranian Registry of Clinical Trials

05 Jun 2026

The comparision effect of Achillea millefolium products on traditional medicine base, with clotrimazole cream 1% on vaginal candidiasis.

Protocol summary

Study aim

This study is a clinical trial to investigate the effect of Achillea millefolium based on Traditional Medicine on vaginal candidiasis.

Design

In this research, 70 eligible patients referring to the Fatima Al-zahra Infertility Center of Babol University of Medical Sciences were chosen purposefully and a code was allocated to each one of them. Then, patients were randomly divided into two control and intervention groups.

Settings and conduct

This study will be conducted in two groups in parallel for one month. The number of participants in each group is 35. With the approval of a Gynecologist, patients who have the inclusion criteria will be included in this study with simple consecutive sampling and the participants give their full consent.This triple blind study will be limited to the Fatima Al-zahra Infertility Center that way tubes and creams are quite similar in two groups and investigator, volunteers, and data analyser are unaware of allocation.

Participants/Inclusion and exclusion criteria

The main inclusion criteria are sign and symptoms of vulvovaginal candidiasis; positive smear and culture from vaginal discharges; non-complicated vaginal candidiasis on diagnosis of Gynecologist. The main exclusion criteria is side effects or drug reactions.

Intervention groups

Patients are included in the two groups after confirmation of Candida infection by smear. One group gives aqueous extract of Achillea millefolium and the other group gives clotrimazole cream 1%. Both groups are in form of vaginal cream, an applicator nightly for one week.

Main outcome variables

People in the study before and 7-10 days after the beginning of interventions and 2-3 weeks after the end of interventions will be investigated by self-report ,physical examination, PH, smear and culture from vaginal discharges and probable side effects of the drug and the effect of medication on the mentioned parameters.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20170918036261N1**
Registration date: **2017-11-28, 1396/09/07**
Registration timing: **prospective**

Last update: **2017-11-28, 1396/09/07**
Update count: **0**

Registration date

2017-11-28, 1396/09/07

Registrant information

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Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

babol medical univercity

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-10-23, 1397/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparision effect of Achillea millefolium products on traditional medicine base, with clotrimazole cream 1% on vaginal candidiasis.

Public title

The effect of yarrow vaginal cream on treatment of candida vaginitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

married women,18 to 45 years old The presence of sign and symptoms of candida vulvovaginitis Positive smear from vaginal discharge for candida Positive culture of vaginal discharge for candida

Exclusion criteria:

History of allergy to clotrimazole vaginal cream History of drug allergy Pregnancy Mensturation period Breastfeeding Menopause The presence of chronic underlying diseases: kidney, liver and Heart diseases, Diabetes and Immune deficiency Score 24-30 based on DLQI questionnaire Vulvar erythem score 3 Use of systemic antibiotics, immunosuppressive drugs or other vaginal creams and antifungal drugs during the past 4 weeks Patient's unsatisfactory to participate in the study

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **70**

Randomization (investigator's opinion)

Randomized

Randomization description

The method of randomization in this study is quadruple blocking method and the randomization unit is individual and tool is statistical software. The sequencing will be done by quadruple blocking. Concealing done by using simillar form and size tubes for both groups, and neither the interventions nor the volunteers nor the data analyzer knows how to allocate the intervention.

Blinding (investigator's opinion)

Triple blinded

Blinding description

In this study, patients are completely unaware of which drugs they received. Also, the investigator and data analyzer are completely unaware that the two groups received which drug.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Babol University of Medical Science

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karegar squar., Ganjafrooz street., Babol University of Medical Science., Babol

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Province

Mazandaran

Postal code

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Approval date

2017-08-27, 1396/06/05

Ethics committee reference number

MUBABOL.HRI.REC.1396.83

Health conditions studied

1

Description of health condition studied

Candida vulvovaginitis

ICD-10 code

B37.3

ICD-10 code description

Candidiasis of vulva and vagina

Primary outcomes

1

Description

Burning

Timepoint

At first, 7-10 days after the beginning of interventon and 2-3 weeks after the end of intervention

Method of measurement

Evauation of clinical symptom's remission (burning) with Dermatology Quality of Life Index (DLQI) questionnaire

2

Description

Pruritus

Timepoint

At first, 7-10 days after the begining of interventon and

2-3 weeks after the end of intervention

Method of measurement

Evauation of clinical symptom's remission (pruritus) with Dermatology Quality of Life Index (DLQI) questionnaire

3

Description

Dysparonia

Timepoint

At first, 7-10days after the begining of interventon and 2-3 weeks at the end of intervention

Method of measurement

Evauation the rate of satisfactory from intercourse with Dermatology Quality of Life Index (DLQI) questionnaire

4

Description

Volvar erythema

Timepoint

At first, 7-10days after the begining of interventon and 2-3 weeks at the end of intervention

Method of measurement

Vulvar examination and scoring the erythema of vulva by Gynecologist

Secondary outcomes

1

Description

Result of culture

Timepoint

At first, 7-10 days after the begining of intervention and 2-3 weeks after the end of intervention

Method of measurement

Sampling from vaginal discharges

Intervention groups

1

Description

Intervention group: Vaginal cream 2% of aqueous extract of Achillea millefolium, one applicator at night for 7 nights. Made in Pharmacy Department of Traditional Medicine, College of Traditional Medicine, Babol University of Medical Science

Category

Treatment - Drugs

2

Description

Control group: Vaginal cream of clotrimazol 1% made by the PARS DAROU pharmaceutical company; Tehran, IRAN. One applicator at night for 7 nights.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatima Al-zahra Infertility and Reproductive Health Research Center

Full name of responsible person

Doctor Sedighe Esmaeelzade

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research Babol University of Medical Sciences

Full name of responsible person

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moghadamnia@yahoo.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research Babol 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

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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