Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of marigold (Calendula) and metronidazol on bacterial vaginitis in reproductive women in Dezful health care centers

Protocol summary

Summary

The study is a double-blind randomized controlledtrial aimsto compare to effect of marigold vaginal cream and metronidazole in the treatment of bacterial vaginosis. In this study, 78 non-pregnant married women 45-18 years old with bacterial vaginosiswillrandomly recruitedin two treatment groups (39 women in each group). Diagnostic criteria for bacterial vaginosiswill be having three positive criteria from AMSEL parameters as follow:(homogeneous vaginal discharge, PH of vagina ≥4.5, positive Whiff test, presence of key cells invaginal wet smear). The intervention group(n = 39) will receive marigold vaginal cream (oneapplicator= 5 gr) once a day and the metronidazole group (n = 39) will receive metronidazole vaginal cream (oneapplicator= 3 gr) once a dayfor 7 days. Patients willadvised to come back for follow up 7 days after completion of treatment. In the follow-up visit all women will be assessed regarding treatment and a check list also will be completed.A wet smear and a sample for culture will be obtained in the follow-up visit. All results will be recorded in the check list of each participant. .Patients will be considered treated if they have less than three positive AMSEL criteria.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015082921414N3**
Registration date: **2015-12-01, 1394/09/10**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2015-12-01, 1394/09/10

Registrant information

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Nosrat Bahrami
Name of organization / entity
Dezful University of Medical Sciences
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Deputy for research Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2015-11-21, 1394/08/30

Expected recruitment end date

2016-02-19, 1394/11/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of marigold (Calendula) and metronidazol on bacterial vaginitis in reproductive women in Dezful health care centers

Public title

The effect of marigold (Calendula) on bacterial vaginitis

Purpose

Treatment

Inclusion/Exclusion criteria

reproductive age; marriage; Bacterial vaginosis infection; The pregnancy; no history of chronic disease

Age

No age limit
Gender
Female

Phase
1-2
Groups that have been masked
No information
Sample size
Target sample size: **78**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Deputy for research Ahvaz Jundishapur University of Medical Sciences
Street address
Ahvaz.Golestan BLV. Ahvaz Deputy jun University of Medical Sciences, ground floor
City
Ahvaz
Postal code
Approval date
2015-08-11, 1394/05/20
Ethics committee reference number
IR.AJUMS.REC.1394.302

Health conditions studied

1

Description of health condition studied
bacterial vaginitis
ICD-10 code
N76.0
ICD-10 code description
Acute vaginitis

Primary outcomes

1

Description
vaginal discharge
Timepoint
Before the intervention, a week after intervention
Method of measurement
observation

2

Description
The acidity of vagina
Timepoint
Before the intervention, a week after intervention
Method of measurement
PH meter tape

3

Description
wiff test
Timepoint
Before the intervention, a week after intervention
Method of measurement
Potassium hydroxide solution 10%

4

Description
number key cells
Timepoint
Before the intervention, a week after intervention
Method of measurement
pao smear

Secondary outcomes

empty

Intervention groups

1

Description
intervention 2, metronidazole vaginal cream (an applicator 3 mg) once a day for 7 days. Brand: metromax, Company: chemidaru
Category
Treatment - Drugs

2

Description
Intervention 1, vaginal cream marigold (an applicator 5 mg) once a day for a week, Manufacturer: Tehran University of Medical Sciences
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Nahal Midwifery counseling and health care services

Full name of responsible person
Seyedeh Zahra Pazhohideh
Street address
Afarinesh street, Opposite Contacts, Adjacent to the Ultrasound doctor Behzadi
City
Dezful

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Deputy for research Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
Moustafa Feghhi
Street address
Ground Floor, Ahvaz Research and Technology Development Department of Jundishapur University of Medical Sciences, Golestan Blvd. Ahvaz
City
Ahvaz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Deputy for research Ahvaz Jundishapur University of Medical Sciences
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
Ahvaz Jundishapur University of Medical Sciences
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Person responsible for updating data

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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