

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 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 controlled trial 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  $\geq 4.5$ , 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

##### Name

Nosrat Bahrami

##### Name of organization / entity

Dezful University of Medical Sciences

##### Country

Iran (Islamic Republic of)

##### Phone

+98 64 1626 9532

##### Email address

bahrami.n@dums.ac.ir

#### 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**

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**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**

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**Web page address****Person responsible for scientific inquiries****Contact****Name of organization / entity**Shoushtar Medical faculty .Ahvaz Jundishapur  
University of Medical Sciences**Full name of responsible person**

Seyedeh Zahra Pazhohideh

**Position**

master of science midwifery

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**Web page address****Sponsors / Funding sources****1****Sponsor****Name of organization / entity**Deputy for research Ahvaz Jundishapur University of  
Medical Sciences**Full name of responsible person**

Moustafa Fegghi

**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

**Full name of responsible person**

Seyedeh Zahra Pazhohideh

**Position**

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**Position**

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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*