Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Nov 2026

The effect of Henna (Lawsonia inermis) vaginal suppository combined with antibiotic therapy in the treatment of cervicitis : A Randomized Triple-blind Clinical Trial

Protocol summary

Study aim

Comparison the efficacy of oral Azithromycin, Cefixime and Metronidazole with vaginal suppository of Henna oil based in women with cervicitis

Design

This is a triple-blind randomized clinical trial, phase III, in which 92 eligible patients will be randomly assigned to the intervention and control groups.

Settings and conduct

Patients with cervicitis referred to Shahid Sadoughi Hospital in Yazd and Ardakan School of Persian Medicine will be included in the study if they are eligible and will be randomly assigned to the intervention and control groups. This trial will be triple-blinded so that neither patients nor the examining physician nor statistical analysts will be aware of the intervention.

Participants/Inclusion and exclusion criteria

Inclusion criteria: non-menopausal women ; cervicitis; married. Exclusion criteria: menopause; pregnancy; breastfeeding; any addiction; observe herpes sores or genital warts on examination and/or HPV positive test; concomitant use of antibiotic or herbal remedies for her disease (do not take antibiotic, immunosuppressive drugs or vaginal medications for 14 days before study); history of allergies to henna

Intervention groups

Intervention group: Cefexime tab 400 mg single dose, azithromycin tab 1 mg single dose and metronidazole tab 500 mg every 12 hours for 5 days and vaginal suppository of Henna oil based every night for a week and couples treated with cefixime 400 mg single dose, azithromycin 1 mg single dose and 4 metronidazole 500 mg single dose. Control group: Cefexime 400 mg single dose, azithromycin 1 mg single dose and metronidazole 500 mg every 12 hours for 5 days and basic suppository for 1 week, 1 each night and spouses similar to the intervention group.

Main outcome variables

Cervical ulcer size; Discharge; Irritation; Dyspareunia; Postcoital bleeding; Friability

General information

Reason for update

Since the sampling was done during the COVID-19 crisis and the possibility of further loss of patients in the process، we increased the number of patients.

Acronym

IRCT registration information

IRCT registration number: **IRCT20210312050686N1**
Registration date: **2021-07-13, 1400/04/22**
Registration timing: **prospective**

Last update: **2024-04-10, 1403/01/22**
Update count: **3**

Registration date

2021-07-13, 1400/04/22

Registrant information

Name

naeeme nabi meybodi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3823 3995

Email address

n.nabimeybodi@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-08-06, 1400/05/15

Expected recruitment end date

2021-10-23, 1400/08/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of Henna (Lawsonia inermis) vaginal suppository combined with antibiotic therapy in the treatment of cervicitis : A Randomized Triple-blind Clinical Trial

Public title

Effect of Henna vaginal suppository combined with antibiotic therapy in the treatment of cervicitis

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

married non-menopausal women who confirme cervicitis through colposcopy and biopsy with symptoms such as refractory vaginal discharge, postcoital bleeding (PCB), abnormal uterine bleeding (AUB), abnormal Pap smear, or abnormal appearance of the cervix on examination with a speculum.

Exclusion criteria:

being pregnant lactating involved in any addiction observing herpes sores or genital warts on examination and/or HPV positive test dysplasia or cancer of cervix intake of herbal products or medications that influence cervicitis like antibiotics, immunosuppressive drugs or vaginal medications over 2 weeks before the commencement of the study history of allergies to Henna

Age

From **21 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: **92**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients are randomly assigned to the intervention and control groups through random sequences generated by random allocation software.

Blinding (investigator's opinion)

Triple blinded

Blinding description

This is a triple-blind controlled clinical trial. The pharmacist identifies the drug and the placebo with two types of codes A and B. Researcher, patients, and statistical analysts do not know whether A or B is a drug or a placebo. Therefore, the researcher, patients and statistical analyst are kept blind until the end of the study. At each visit, patients are randomly assigned to group A or B. People will not know how to distribute the drug and the drugs are available to patients in opaque colored bottles with a similar shape and sealed according to the codes defined randomly. The tools and materials needed to make the placebo will be exactly the same as the medicine except that only the active ingredient is removed from the placebo.

Placebo

Used

Assignment

Parallel

Other design features

The effect of the studied drug has been extracted from reliable sources of traditional Iranian medicine.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Yazd Shahid Sadoughi University of Medical Sciences

Street address

Yazd University of Medical Sciences, Bahonar Square, Yazd

City

Yazd

Province

Yazd

Postal code

8916978477

Approval date

2020-10-27, 1399/08/06

Ethics committee reference number

IR.SSU.REC.1399.193

Health conditions studied

1

Description of health condition studied

Cervicitis

ICD-10 code

Inflammato

ICD-10 code description

N72

Primary outcomes

1

Description

Mean of ulcer size

Timepoint
Before the intervention, after completion of the intervention
Method of measurement
Clinical examination

Secondary outcomes

1

Description
Vaginal discharges
Timepoint
Before the intervention, after completion of the intervention
Method of measurement
Visual Analogue Scale

2

Description
Irritation
Timepoint
Before intervention, after intervention
Method of measurement
Visual Analogue Scale

3

Description
Dyspareunia
Timepoint
Before intervention, after intervention
Method of measurement
Yes- no

4

Description
Postcoital bleeding
Timepoint
Before intervention, after intervention
Method of measurement
Yes- no

5

Description
Friability
Timepoint
Before intervention, after intervention
Method of measurement
Yes- no

Intervention groups

1

Description
Intervention group: Cefixime 400 mg single dose, azithromycin 1 mg single dose and metronidazole 500 mg every 12 hours for 5 days and vaginal suppository of Henna oil based every night for a week and partner cefixime 400 mg single dose, azithromycin 1 mg single dose and 4 metronidazole 500 mg
Category
Treatment - Drugs

2

Description
Control group: Cefixime 400 mg single dose, azithromycin 1 mg single dose and metronidazole 500 mg every 12 hours for 5 days and placebo one every night for a week and partner Cefixime 400 mg single dose, Azithromycin 1 mg single dose and 4 metronidazole 500 mg
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Specialized Poly-Clinic Of Baghaei Pour
Full name of responsible person
Naeeme Nabi Meybodi
Street address
Specialized Poly-Clinic of Baghaei Pour, Shahid Ghandi Blvd, Safaieh, Yazd
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baghaei@ssu.ac.ir

2

Recruitment center
Name of recruitment center
Ardakan School of Persian Medicine
Full name of responsible person
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Ardakan School of Persian Medicine, Imam Khomeini Ave, Ardakan
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Email
tebsonati@ssu.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd University of Medical Sciences
Full name of responsible person
Masoud Mirzaee
Street address
Yazd University of Medical Sciences, Bahonar Square
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Email
dvc.research@ssu.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yazd 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
Yazd University of Medical Sciences
Full name of responsible person
Naeeme Nabi Meybodi
Position
PhD student
Latest degree
Medical doctor
Other areas of specialty/work
Traditional Medicine
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Person responsible for updating data

Contact
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Position
PhD student
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Other areas of specialty/work
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dvc.research@ssu.ac.ir

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