Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Comparison of the effect of standard antibiotic treatment and antibiotic treatment adding vaginal honey in In patients with cervicitis who referred to Mousavi Hospital in Zanjan

Protocol summary

Study aim

Determine and comparison of the effect of standard antibiotic treatment and antibiotic treatment adding vaginal honey in In patients with cervicitis who referred to Mousavi Hospital in Zanjan

Design

Clinical trials with control group, community based and performance with parallel, double blind, randomized groups, and 51 subjects in each group.

Settings and conduct

This is a double-blind randomized clinical trial that was performed in all patients with cervicidity referred to Ayatollah Mousavi Hospital in Zanjan. In this study, the researcher and patient were blinded.

Participants/Inclusion and exclusion criteria

Include criteria: women non-pregnant -Having symptoms and clinical findings of cervicitis -age of 15-45 years Exclude criteria: Honey sensitivity Abnormal Pap Smear Antibiotic use in the last two weeks PID Diseases such as diabetes and immune deficiency Consumption of corticosteroids

Intervention groups

Placebo and antibiotic groups: Placebo formulation was used for 5 days each night with an applicator for 2 weeks. Antibiotic therapy in both groups included oral azithromycin per gram of single dose and oral single dose 400 mg oral cefaxime with sexual partner therapy. Vaginal honey group and antibiotic: Honey formulation was used every 5 days with an applicator for 2 weeks. Antibiotic therapy in both groups included oral azithromycin, one gram of single dose, and single dose 400 mg oral cefaxime with sexual partner therapy.

Main outcome variables

Pain intensity; Erosion

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180707040370N3**
Registration date: **2018-10-12, 1397/07/20**
Registration timing: **retrospective**

Last update: **2018-10-12, 1397/07/20**
Update count: **0**

Registration date

2018-10-12, 1397/07/20

Registrant information

Name

Ensiyeh Jenabi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 81 3838 0496

Email address

e.jenabi@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-25, 1396/11/05

Expected recruitment end date

2018-04-20, 1397/01/31

Actual recruitment start date

2018-01-25, 1396/11/05

Actual recruitment end date

2018-04-20, 1397/01/31

Trial completion date

2018-04-20, 1397/01/31

Scientific title
Comparison of the effect of standard antibiotic treatment and antibiotic treatment adding vaginal honey in In patients with cervicitis who referred to Mousavi Hospital in Zanjan

Public title
Comparison of the effect of standard antibiotic treatment and antibiotic treatment adding vaginal honey in In patients with cervicitis

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
women non-pregnant Having symptoms and clinical findings of cervicitis age of 15-45 years

Exclusion criteria:
Honey sensitivity Abnormal Pap Smear Antibiotic use in the last two weeks PID Diseases such as diabetes and immune deficiency Consumption of corticosteroids

Age
From **15 years** old to **45 years** old

Gender
Female

Phase
2

Groups that have been masked

- Participant
- Investigator

Sample size
Target sample size: **102**
Actual sample size reached: **102**

Randomization (investigator's opinion)
Randomized

Randomization description
Participants were randomly assigned to the two groups of 50 recipients of antibiotic and vaginal honey and other group antibiotic and placebo using the Select (randbetween (1; 2) command, using the Excel computer program).

Blinding (investigator's opinion)
Double blinded

Blinding description
The drug packages are similar and the third partner is planning to provide the students with a post-training course on how to use and how to complete the drug questionnaire. This person does not know the contents inside which group is concerned so neither the researcher nor the participants knows the contents of the package and the person will be blinded to the two sides.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Zanjan University of Medical Sciences

Street address
Azadi Blvd, Zanjan University of Medical Sciences

City
زنجان

Province
Zanjan

Postal code
4515613191

Approval date
2018-01-23, 1396/11/03

Ethics committee reference number
IR.ZUMS.REC.1396.270

Health conditions studied

1

Description of health condition studied
Cervicitis

ICD-10 code
N72

ICD-10 code description
Inflammatory disease of cervix uteri

Primary outcomes

1

Description
pain intensity

Timepoint
Before intervention and 21 days after intervention

Method of measurement
Based on the Visual Analuoge Scale pain intensity

2

Description
Erosion examination

Timepoint
Before intervention and 21 days after intervention

Method of measurement
Take a picture

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The capsule Azythromycin is

receiving 1g capsules single dose and Tablet Cefixime 400mg single dose and vaginal Gel of honey formulation per night 5 cc for 2 weeks

Category

Treatment - Drugs

2

Description

Control group: the capsule Azythromycin is receiving 1g capsules single dose and Tablet Cefixime 400mg single dose and vaginal Gel of Placebo formulation is receiving per night 5 cc for 2 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center
gynecological clinic of Mousavi Hospital in Zanjan

Full name of responsible person
Nazanin Soltani

Street address
Gavazang Ave, Mousavi Hospital

City
زنجان

Province
Zanjan

Postal code
4515613191

Phone
+98 24 3313 0001

Email
dr.nazaninsoltani@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Zanjan University of Medical Sciences

Full name of responsible person
Alireza Shoghli

Street address
Azadi Blvd, Zanjan University of Medical Sciences

City
زنجان

Province
Zanjan

Postal code
4515613191

Phone
+98 24 3342 0677

Email
shoghli@zums.ac.ir

Grant name

Grant code / Reference number

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

Title of funding source
Zanjan 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
Zanjan University of Medical Sciences

Full name of responsible person
Nazanin Soltani

Position
Consultant

Latest degree
Medical doctor

Other areas of specialty/work
Gynecology and Obstetrics

Street address
Azadi Blvd, Zanjan University of Medical Sciences

City
زنجان

Province
Zanjan

Postal code
4515613191

Phone
+98 24 3342 0677

Email
dr.nazaninsoltani@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity
Zanjan University of Medical Sciences

Full name of responsible person
Nazanin Soltani

Position
Consultant

Latest degree
Medical doctor

Other areas of specialty/work
Gynecology and Obstetrics

Street address
Azadi Blvd, Zanjan University of Medical Sciences

City
زنجان

Province
Zanjan

Postal code
4515613191
Phone
+98 24 3342 0677
Email
dr.nazaninsoltani@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Hamedan University of Medical Sciences
Full name of responsible person
Ensiyeh Jenabi
Position
Associate professor
Latest degree
Ph.D.
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Shahid Fahmideh Ave, Hamadan University of Medical Sciences
City
Hamadan
Province
Hamadan
Postal code
65178
Phone
+98 81 3838 0150
Email
en.jenabi@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not 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
Yes - There is a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
A portion of the information, such as information on the main outcome or the like, can be shared.
When the data will become available and for how long
Start the access period 6 months after printing the results
To whom data/document is available
Researchers working in academia
Under which criteria data/document could be used
Any analysis on the data is pertinent with the source.
From where data/document is obtainable
Zanjan University of Medical Sciences
What processes are involved for a request to access data/document
6 months after printing results
Comments