

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

11 Jul 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 cervicity 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 Analogue 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

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**Postal code**  
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**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