Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Studying the effect of amniotic disc combined with standard antibiotics on improving cervicitis symptoms in women of reproductive age: A randomized controlled trial

Protocol summary

Study aim
Determining the effect of amniotic disc on cervicitis symptoms.

Design
Clinical trial with control group, parallel, unblinded, randomized, without reference on 76 patients. Randomization with the rand function of Excel software.

Settings and conduct
In the women's clinic of Qom, two groups will be studied using a three-part data collection tool. From all individuals with the inclusion criteria, a Pap smear sample will be taken by the researcher and after confirmation by a gynecological oncologist (research assistant), both intervention and control groups will receive standard antibiotics; in the intervention group, an amniotic disc will be placed on the cervical wound; then, with an evaluation of the second and sixth weeks, both groups will be studied.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Married women of reproductive age 15-45 years with symptoms of cervicitis. Exclusion criteria: Non-compliance with treatment and presence of abnormal pelvic conditions.

Intervention groups
The intervention group includes women with cervicitis who receive standard antibiotic treatment including azithromycin 1g (Sanamed Pharmaceutical Company) and cefixime 400mg (Kowsar Pharmaceutical Company) as a single oral dose, along with treatment of the sexual partner with the same regimen. In addition, this group also receives a single amniotic disc (manufactured by Sinacel Company) vaginally. • The control group includes women with cervicitis who receive the same standard antibiotic treatment alone including azithromycin 1g and cefixime 400mg (both as a single oral dose) along with treatment of the sexual partner with the same antibiotic regimen.

Main outcome variables
Vaginal mucopurulent discharge; Vaginal itching; Vaginal burning; Pain during vaginal intercourse; Bleeding after vaginal intercourse; Cervical ulcer size; Severity of cervicitis symptoms; Satisfaction

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20250527065922N1**
Registration date: **2025-06-08, 1404/03/18**
Registration timing: **registered_while_recruiting**

Last update: **2025-06-08, 1404/03/18**
Update count: **0**

Registration date
2025-06-08, 1404/03/18

Registrant information

Name
Fatemeh Jeddi

Name of organization / entity

Country
Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2025-05-27, 1404/03/06

Expected recruitment end date
2025-08-28, 1404/06/06

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Studying the effect of amniotic disc combined with standard antibiotics on improving cervicitis symptoms in women of reproductive age: A randomized controlled trial

Public title
The effect of amniotic disc in treating cervicitis symptoms
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Inclusion criteria: 1) Married women of reproductive age 15-45 years. 2) Presence of symptoms of cervicitis including: pain during vaginal intercourse bleeding after vaginal intercourse vaginal itching vaginal burning purulent vaginal mucus discharge erosion (cervical ulcer).
Exclusion criteria:
Non-adherence to treatment (the importance of regular treatment will be explained to the research unit and further explanations regarding adherence to treatment will be provided during the telephone call and follow-up). History of pelvic surgery. Pregnancy and breastfeeding. Cervical polyps and fibroids or other diseases related to the cervix. Any cervical malignancy and abnormal cells in a Pap smear test.
Age
From **15 years** old to **45 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **76**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, stratified randomization with individual randomization was used. Participants were stratified based on three key variables: 1. Education level (diploma and less/higher than diploma) 2. Severity of cervicitis symptoms (0-4, 5-10) 3. Number of sexual intercourses per week (once or less, 2-3 times, 4 times or more) In each stratum, a random number table will be used to assign participants to two groups A and B. In this way: • Numbers between 1 and 4 were assigned to group AB • Numbers between 5 and 10 were assigned to group BA . This process will be performed separately in all combinations of the above strata (total of 12 strata). Allocation to groups was performed by an impartial person independent of the research team who will assign participants to the study groups solely based on a pre-prepared random sequence. This method will maintain allocation concealment as much as possible and prevent bias in patient enrollment.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Khorramabad University of Medical Sciences
Street address
Qom, Enqelab blvd, After Alley 14, No. 380
City
Qom
Province
Ghoum
Postal code
3715718979
Approval date
2025-05-27, 1404/03/06
Ethics committee reference number
IR.LUMS.REC.1404.050

Health conditions studied

1

Description of health condition studied
Women with cervicitis
ICD-10 code
N72
ICD-10 code description
Inflammatory disease of cervix uteri

Primary outcomes

1

Description
Severity of cervicitis symptoms
Timepoint
Pre-study, second week, and sixth week assessments
Method of measurement
Questionnaire, Visual Analogue Scale

2

Description
Size of the cervical scar
Timepoint
Pre-study, second week, and sixth week assessments
Method of measurement
Visual examination

Secondary outcomes

1

Description
Pain during vaginal intercourse
Timepoint
Pre-study, the second and sixth weeks of assessment
Method of measurement
Questionnaire, Visual Analogue Scale

2

Description
Bleeding after vaginal intercourse
Timepoint
Pre-study, the second and sixth weeks of assessment
Method of measurement
Questionnaire, Visual Analogue Scale

3

Description
Vaginal itching
Timepoint
Pre-study, the second and sixth weeks of assessment
Method of measurement
Questionnaire, Visual Analogue Scale

4

Description
Vaginal burning
Timepoint
Pre-study, the second and sixth weeks of assessment
Method of measurement
Questionnaire, Visual Analogue Scale

5

Description
Vaginal purulent mucous discharge
Timepoint
Pre-study, the second and sixth weeks of assessment
Method of measurement
Questionnaire, Visual Analogue Scale

6

Description
Satisfaction
Timepoint
the second and sixth weeks of assessment
Method of measurement
Questionnaire, Visual Analogue Scale

7

Description
Number of vaginal intercourses per week
Timepoint
Pre-Study
Method of measurement
Questionnaire

Intervention groups

1

Description
• Intervention group: Participants in this group will receive standard antibiotics including cefixime 400 mg orally (single dose, Kowsar Company) and azithromycin 1 g orally (single dose, Thanamed Company). Each participant's sexual partner will also be treated with a similar antibiotic regimen. In addition to drug treatment, a single amniotic disc will be used in this group. The amniotic disc, derived from the human fetal amniotic membrane, is prepared by Sinacell Company, dried and sterilized. Treatment will begin after the end of menstrual bleeding. Patients are advised to refrain from sexual intercourse for two weeks. For the intervention, the patient is placed in the lithotomy position and the amniotic disc is placed on the cervical erosion area under sterile conditions using forceps. After 15 to 20 minutes of absorption, the dressing is applied and the patient can get out of bed.
Category
Treatment - Other

2

Description
Control group: Participants in this group will receive cefixime 400 mg orally (single dose, Kowsar Company) and azithromycin 1 g orally (single dose, Thanamed Company). Their sexual partners will also be treated with the same antibiotic. Treatment will begin after the end of menstrual bleeding. Patients are advised to abstain from sexual intercourse for two weeks. No other physical intervention or complementary therapy will be performed in this group.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Women's Clinic affiliated with Qom University of Medical Sciences
Full name of responsible person
Fatemeh Jaddi
Street address

Qom, Enqelab blvd, After Alley 14, No. 380

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Khoram-Abad University of Medical Sciences

Full name of responsible person
Dr. Bahram Kamrei

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Qom, Enqelab blvd, After Alley 14, No. 380

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Grant name

Grant code / Reference number

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

Title of funding source
Khoram-Abad 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
Khoram-Abad University of Medical Sciences

Full name of responsible person
Fatemeh Jeddi

Position
Master's degree student in midwifery

Latest degree
Bachelor

Other areas of specialty/work
Midwifery

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Khoram-Abad University of Medical Sciences

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Fatemeh Jeddi

Position
Master's degree student in midwifery

Latest degree
Bachelor

Other areas of specialty/work
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Person responsible for updating data

Contact

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Position
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Latest degree
Bachelor

Other areas of specialty/work
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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