Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

A comparative study of the effect of amniotic pads and cryo on the treatment of cervicitis in patients with cervicitis: A Clinical Trial Study

Protocol summary

Study aim
Investigating the effect of amniotic pads on cervicitis
Design
This clinical trial type study with a control group, with parallel groups, double-blind, randomized, phase 2 will be performed on 100 patients.
Settings and conduct
In this study, people referring to private clinics in Ardabil city will be included in the study based on symptoms and clinical examination and pap smear results, who have mild and moderate cervicitis.The study is double-blind, which means that both the patient and the doctor will be unaware of the type of treatment. For group A, the amniotic membrane pad will be completely placed on the cervical wound under a colposcopy guide or the naked eye. After 3 weeks, a visit and examination will be done. Group B (cryotherapy) will undergo the usual cryotherapy treatment.
Participants/Inclusion and exclusion criteria
Inclusion criteria: - Married women and having an age of 20-55 years -Women with acute and chronic cervicitis referring to the office based on clinical examination - Pap smear test results indicate mild or moderate cervicitis Exclusion criteria: -Women with a positive pap smear test for malignancy and CIN - Pregnant women
Intervention groups
Experimental group A will be treated with amniotic pads and control group B will be treated with cryo (50 people in each group).
Main outcome variables
cervicitis

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20240706062338N1**
Registration date: **2024-07-17, 1403/04/27**
Registration timing: **prospective**

Last update: **2024-07-17, 1403/04/27**
Update count: **0**
Registration date
2024-07-17, 1403/04/27

Registrant information
Name
Roya Motavalli
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2024-07-19, 1403/04/29
Expected recruitment end date
2024-10-20, 1403/07/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
A comparative study of the effect of amniotic pads and cryo on the treatment of cervicitis in patients with cervicitis: A Clinical Trial Study

Public title
Investigating the effect of amniotic pads on the treatment of cervicitis

Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
- Married women and having an age of 20-55 years - Patient consent to participate in this study -Women with acute and chronic cervicitis referring to the office based on clinical examination - Pap smear test results indicate mild or moderate cervicitis
Exclusion criteria:
-Women with a positive pap smear test for malignancy and CIN - Pregnant women - Abnormal result of cervical biopsy Vaginal spotting or bleeding of unknown cause Chronic infection of unknown cause - Menstrual bleeding
Age
From **20 years** old to **55 years** old
Gender
Female

Phase
N/A
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **100**
Randomization (investigator's opinion)
Randomized
Randomization description
In this study, women aged 20-55, based on symptoms and clinical examination and pap smear results, have mild and moderate cervicitis, in two treatment groups: an experimental group treated with amniotic pads and a control group, treated with cryo (in each group 50 people) will be. The samples will be selected using random sampling method. The samples will be distributed in such a way that two types of colored cards will be printed according to the number of samples in each group, and women will choose one of the cards upon entering the study and will be randomly distributed among the two groups according to the color of the card. The patient and the relevant doctor will not know the type of special color card and the study will be double-blind.
Blinding (investigator's opinion)
Double blinded
Blinding description
In this study, women aged 20-55, based on symptoms and clinical examination and pap smear results, have mild and moderate cervicitis, in two treatment groups: an experimental group treated with amniotic pads and a control group, treated with cryo (in each group 50 people) will be. Written consent will be obtained from eligible research units to participate in the research.The samples will be selected using random sampling method. The samples will be distributed in such a way that two types of colored cards will be printed according to the number of samples in each group, and women will choose one of the cards upon entering the study and will be randomly distributed among the two groups according to the color of the card. The patient and the relevant doctor will not know the type of special color card and the study will be double-blind.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Committee of ethics in research of Islamic Azad University-Ardebil branch
Street address
Basij Square., Islamic Azad University of Ardabil branch
City
Ardabil
Province
Ardabil
Postal code
5615731567
Approval date
2024-04-16, 1403/01/28
Ethics committee reference number
IR.IAU.ARDABIL.REC.1403.012

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
Cervicitis
Timepoint
In this study, those who have mild and moderate cervicitis based on clinical examination and pap smear results will be included in the study. 3 weeks after the treatment, the visit and examination will be done again.
Method of measurement
Clinical symptoms, clinical examination, pap smear results

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: The experimental group will be treated with amniotic pads. After the clinical examination and pap smear and definitive diagnosis of cervicitis, the cervix will be washed and moistened with normal saline under direct vision. Then, the amniotic membrane pad will be completely placed on the cervical wound under a colposcopy guide or the naked eye. Then a piece of Vaseline will be placed on the pad. After a day, the vaseline gas will come out. 3 weeks later, the visit and examination will be done again. This process will be done twice if necessary.The amniotic disc manufacturer is Sinacell, a knowledge-based company, and its product number is AMD020830- 03.

Category

Treatment - Other

2

Description

Control group: They will be treated with cryo.The doctor inserts a tool called a cryoprobe into the vagina and presses it on the cervix for 3 minutes. Nitrogen gas at a temperature of -50 degrees Celsius cools the metal and creates an ice ball on the cervix, this ice ball destroys abnormal cells.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Private office of Dr. Shabnam Jafari Zare, gynecologist and obstetrician

Full name of responsible person
Dr. Shabnam Jafari Zare

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First floor., Azarbaijan Building., Aref Alley., Sarcheshmeh St

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Islamic Azad University

Full name of responsible person
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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
Islamic Azad University

Proportion provided by this source
100

Public or private sector
Private

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
Islamic Azad University

Full name of responsible person
Roya Motavalli

Position
Instructor, Department of Midwifery

Latest degree
Master

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