

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

Comparison of the therapeutic effect of tranexamic acid with cryotherapy in the treatment of symptoms of cervical ectropion in patients referred to the gynecology clinic of Ayatollah Mousavi Hospital in Zanjan during 2022 and 2023: a randomized clinical trial study

Protocol summary

Study aim

Determining the therapeutic effects of tranexamic acid in comparison with cryotherapy in patients with symptoms caused by cervical ectropion

Design

This clinical trial with parallel groups, single blind, randomized, phase 3 will be performed on 88 patients. A random number table will be used for randomization. Patients with cervical erosion who meet the inclusion criteria will be randomly divided into two groups: tranexamic acid and cryotherapy.

Settings and conduct

This study will be performed as a randomized clinical trial during 2022 and 2023 on patients with cervical ectropion referred to the gynecology clinic of Ayatollah Mousavi Hospital in Zanjan. The study will be single blind, and the data analyst and the person writing the draft will be unaware of the intervention. In the study group participants, 500 mg of tranexamic acid in the form of a vaginal tablet will be placed in the cervical region with an applicator. Patients are asked to visit on a weekly basis in the first month and then monthly for up to three months. In the control group, cryotherapy will be performed. Patients are asked to visit in the first week after menstrual period. Cryotherapy will be performed using liquid nitrogen / carbon dioxide at zero temperature. Patients will be placed in a lithotomy position.

Participants/Inclusion and exclusion criteria

Non-pregnant women with symptoms of cervical ectropion, including mucoprolant secretions, postpartum hemorrhage, and pelvic pain, who have not responded to routine antibiotic therapy and are between 18 and 45 years old, will be included in the study. Exclusion criteria include: pregnancy, menopause, contraceptive use, IUD, history of known malignancies.

Intervention groups

Administration of 500 mg tranexamic acid daily as a vaginal tablet for ten days

Main outcome variables

Pelvic pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220115053719N1**

Registration date: **2022-02-07, 1400/11/18**

Registration timing: **prospective**

Last update: **2022-02-07, 1400/11/18**

Update count: **0**

Registration date

2022-02-07, 1400/11/18

Registrant information

Name

Farzaneh Hekmatfar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 24 3332 4059

Email address

hekmatfar.farzaneh@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-03-20, 1400/12/29

Expected recruitment end date

2022-08-27, 1401/06/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the therapeutic effect of tranexamic acid with cryotherapy in the treatment of symptoms of cervical ectropion in patients referred to the gynecology clinic of Ayatollah Mousavi Hospital in Zanjan during 2022 and 2023: a randomized clinical trial study

Public title

Tranxamic acid in cervical ectropion

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients who have been diagnosed with cervical ectropion by an experienced gynecologist.

Exclusion criteria:

Pregnancy Having any known malignancy Patients in the Menopause period Intrauterine device (IUD) Taking contraceptives in the recent 3 months

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

3

Groups that have been masked

- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **88**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, we will use Random number table. We will use concealment allocation, so the assigned group will be unknown. Using opaque, sealed envelopes will be assigned in a random sequence. Finally, the envelopes will be opened respectively and the assigned group of the participant will be revealed.

Blinding (investigator's opinion)

Single blinded

Blinding description

Data collectors, outcome assessors, and with lessor importance Data Safety and Monitoring Board and manuscript writers will be blinded about interventions.

Placebo

Not 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

Jomhori blvd., Azadi Sq.

City

Zanjan

Province

Zanjan

Postal code

9357118613

Approval date

2022-01-12, 1400/10/22

Ethics committee reference number

IR.ZUMS.REC.1400.428

Health conditions studied**1****Description of health condition studied**

Cervical ectropion

ICD-10 code

N86

ICD-10 code description

Erosion and ectropion of cervix uteri

Primary outcomes**1****Description**

Pelvic pain

Timepoint

Patients' pain will be evaluated at intervals of zero, the seventh day, the fourteenth day, the twenty-first day, the twenty-eighth day, the sixtieth day and the ninetieth day.

Method of measurement

Visual Analogue Scale will be used to determine the pain.

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: 500 mg Tranexamic Acid vaginal tablet daily for 10 days

Category

Treatment - Drugs

2

Description

Control group: cryotherapy, The cryotherapy probe will be selected based on the size and location of the erosion. Cryotherapy will be performed using liquid nitrogen / carbon dioxide at zero temperature. Patients will be placed in a lithotomy position, cryotherapy will be performed by the gynecologist in charge of the project. The probe will be placed for 3 to 5 minutes.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Mousavi Hospital in Zanjan

Full name of responsible person

Farzaneh HekmatFar

Street address

Ayatollah Mousavi Hospital. Gavazang Road. Zanjan

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Hekmatfar.farzaneh@zums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zanjan University of Medical Sciences

Full name of responsible person

Faramarz Dobakhti

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Jomhori Blvd., Azadi Sq.

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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

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

Farzane Hekmatfar

Position

resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data

Contact

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

the primary outcome measure would be shared .

When the data will become available and for how long

from 2024

To whom data/document is available

people working in academic institutions

Under which criteria data/document could be used

Raw data is not available to individuals and upon request, the results of the requested statistical analysis will be available to individuals.

From where data/document is obtainable

Contact the research expert of the Infertility Clinic of Zanjan University to receive the required documents or data.

What processes are involved for a request to access data/document

To submit a request, it is enough to contact the mentioned expert and send a written and signed request to her.

Comments