Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

Evaluation the effect of cryotherapy in the treatment of mild cervical dysplasia(grade I) in comparison with the expected treatment in patients who referred to Sabzevar gynecological oncology center

Protocol summary

Study aim

Efficacy of cryotherapy in treatment of mild cervical dysplasia in patients referred to oncology gynecology center of Sabzevar compared to expectant management

Design

This clinical trial with the control group is performed in parallel-group, double-blind, randomized in phase 3 on100 patients.Samples will be randomly assigned to four blocks .

Settings and conduct

This blinded clinical trial was performed in Sabzevar gynecology-oncology clinic on patients with diagnosis of cin1 were already diagnosed by colposcopy.Necessary information, previous reports of pap sear, and colposcopy biopsies are recorded in a questionnaire. The women with CIN1 are just enrolled in the study. They are divided into two equal groups of fifty: control and intervention.The control group receives Cr yo-placebo and the intervention group receives true cryotherapy.Patients are examined before of intervention, and1and 3 months later.Colposcopy and biopsy are done for all of participants 6 months after treatment. Outcome: The main outcome is histology improvement of mild cervical dysplasia which will be compared in two groups statistically through Q-square test.

Participants/Inclusion and exclusion criteria

All women with diagnosis of CIN1 who referred to the gynecology oncology clinic

Intervention groups

Control: The trained operator inserts the prob into the patient's vagina but it does not make contact between the prob and the cervix. After about 3 to 5 minutes, the device turns off and the prob comes out. Intervention: The trained operator takes the cryotherapy prob in contact with the cervix. She holds it for about 3 to 5 minutes until forming ice ball in position for every patient.

Main outcome variables

Mild cervical dysplasia

General information

Reason for update

Acronym

-

IRCT registration information

IRCT registration number: **IRCT20220215054030N1**
Registration date: **2022-04-20, 1401/01/31**
Registration timing: **registered_while_recruiting**

Last update: **2022-04-20, 1401/01/31**
Update count: **0**

Registration date

2022-04-20, 1401/01/31

Registrant information

Name

Elham Jananeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3845 9831

Email address

hbeiki@qiet.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-02-21, 1400/12/02

Expected recruitment end date

2023-08-24, 1402/06/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation the effect of cryotherapy in the treatment of mild cervical dysplasia(grade I) in comparison with the expected treatment in patients who referred to Sabzevar gynecological oncology center

Public title

effect of cryotherapy in the treatment of mild cervical dysplasia(grade I)

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

All women referred to the gynecological oncology center,who were diagnosed with cin1 in the studies Be at least 18 years old Absence of menopause Negative pregnancy test Satisfactory colposcopy or Negative endocervical curettage Lesions limited to the exocervix Satisfaction with cooperation low-grade CIN on the basis of historically

Exclusion criteria:

Failure to complete the course of treatment Do not refer to follow-ups Use other treatments at the same time Pregnancy Extending lesion(s) to the vaginal

Age

From **18 years** old

Gender

Female

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **50**

Randomization (investigator's opinion)

Randomized

Randomization description

Block randomization. Block randomization with block size of four will be used. Random Allocation software will be used to generate the stochastic sequence. According to the randomly generated sequences, patients enter the control group and the intervention group.

Blinding (investigator's opinion)

Double blinded

Blinding description

Patients will be unaware of the type of intervention. The physician who will examine the patients will not be aware of the intervention. Therefore, the trial will be run as double blind.

Placebo

Used

Assignment

Parallel

Other design features

-

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Sabzevar University o f Medical Sciences

Street address

Central building of Sabzevar University of Medical Sciences, tohid shahr St., Sabzevar, Razavi khorasan, Iran.

City

Sabzevar

Province

Razavi Khorasan

Postal code

9617913112

Approval date

2022-02-16, 1400/11/27

Ethics committee reference number

IR.MEDSAB.REC.1400.157

Health conditions studied

1

Description of health condition studied

Mild cervical dysplasia

ICD-10 code

N87.0

ICD-10 code description

Dysplasia of cervix, low grade cin 1

Primary outcomes

1

Description

Mild cervical dysplasia

Timepoint

onset(before & after of intervention) & after7 days& 6 month of intervention

Method of measurement

Questionnaire and examination and pathology results

Secondary outcomes

empty

Intervention groups

1

Description

Control: The trained operator inserts the prob into the

patient's vagina but it does not make contact between the prob and the cervix. After about 3 to 5 minutes, the device turns off and the prob comes out.

Category

Treatment - Other

2

Description

Intervention group: The trained operator takes the cryotherapy prob in contact with the cervix. She holds it for about 3 to 5 minutes until forming ice ball in position for every patient.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Sabzevar gynecological oncology center

Full name of responsible person

Dr Jilla Agah

Street address

Mobini hospital, Kashefi st.

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

Dr Mohhammad hossein Saghi

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Grant name

Vice Chancellor for Research & Technology of Sabzevar University of Medical Sciences

Grant code / Reference number

-

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

Yes

Title of funding source

Sabzevar University of Medical Sciences

Proportion provided by this source

30

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

Sabzevar University of Medical Sciences

Full name of responsible person

Elham jananeh

Position

Genicology&obstractive resident

Latest degree

Medical doctor

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific

inquiries

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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