

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

05 Jul 2026

### The effect of topical Imiquimod5% in treatment of high-grade cervical neoplasias (CIN2,3)

#### Protocol summary

cervical intraepithelial neoplasia

##### Study aim

The purpose of this study is to evaluate the histological response rate of high-grade cervical intraepithelial lesions after using topical imiquimod 5% with the histological response as low-grade cervical intraepithelial neoplasia or less in the LEEP sample. In addition, one of the other goals of this study is to determine a model for predicting the response to Imiquimod treatment in patients with cervical neoplasia.

##### Design

About 80 patients (age 20 to 45 years old) who were diagnosed with high-grade cervical neoplasia (CIN2, 3) by biopsy were selected \*randomly\* and divided into two groups of 40 people using quadruple permutation blocks. They are divided into four groups: 1- the group receiving 5% Imiquimod drug, 2- the group receiving LEEP treatment

##### Settings and conduct

About 80 patients (age 20 to 45 years old) who were diagnosed with high-grade cervical neoplasia (CIN2, 3) by biopsy were selected \*randomly\* and divided into two groups of 40 people using quadruple permutation blocks. 1- the group receiving Imiquimod drug, 2- the group receiving LEEP treatment. For patients in the hospital, once a week with suitable study conditions and equipment, for 12 weeks, Imiquimod 5% (250 mg) cream is used in the transformation zone of the cervix. After that, the patient is subjected to LEEP to determine the response to the treatment, and the regression rate is checked compared to the opposite group. Tissue slides are analyzed and interpreted by a pathologist.

##### Participants/Inclusion and exclusion criteria

Age 20-45 years. Diagnosis of high-grade cervical neoplasia. Obtaining informed consent.

##### Intervention groups

1- The group receiving topical imiquimod 5% 2- The group receiving surgical treatment (LEEP)

##### Main outcome variables

Percentage of histological response as low grade or less

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230811059116N1**

Registration date: **2023-09-23, 1402/07/01**

Registration timing: **prospective**

Last update: **2023-09-23, 1402/07/01**

Update count: **0**

##### Registration date

2023-09-23, 1402/07/01

##### Registrant information

##### Name

Nooshin Sarikhani

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 21 7796 1458

##### Email address

nooshin\_wxw@yahoo.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-10-23, 1402/08/01

##### Expected recruitment end date

2024-05-20, 1403/02/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

### Scientific title

The effect of topical Imiquimod5% in treatment of high-grade cervical neoplasias (CIN2,3)

### Public title

The effect of topical Imiquimod5% in treatment of high-grade cervical neoplasias (CIN2,3)

### Purpose

Treatment

### Inclusion/Exclusion criteria

#### Inclusion criteria:

Age 20-45 years old Diagnosis of high-grade cervical neoplasia (CIN2,3) Obtaining informed consent

#### Exclusion criteria:

Cortone therapy Pregnancy Suppressed immune system due to HIV or organ transplant Prior treatment for HSIL

### Age

From **20 years** old to **45 years** old

### Gender

Female

### Phase

3

### Groups that have been masked

*No information*

### Sample size

Target sample size: **80**

### Randomization (investigator's opinion)

Randomized

### Randomization description

The patients will be randomly assigned to intervention and control groups using block randomization. For this purpose, we will prepare four sheets of paper, writing on two sheets the name of the intervention and on the other two sheets the name of the control. The paper sheets will be pooled, placed in a container, and randomly drawn one at a time for each patient without replacement until all four sheets are drawn. The four paper sheets will be then placed back into the container, and this action repeated until the sample size is reached.

### 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 medical school of Iran University of Medical Sciences

### Street address

Iran University of medical sciences, Hammat highway, Tehran

### City

Tehran

### Province

Tehran

### Postal code

1445613131

### Approval date

2022-11-09, 1401/08/18

### Ethics committee reference number

IR.IUMS.FMD.REC.1401.411

## Health conditions studied

### 1

#### Description of health condition studied

The recovery rate of high-grade cervical neoplasias

#### ICD-10 code

#### ICD-10 code description

## Primary outcomes

### 1

#### Description

Cervical intraepithelial neoplasia (CIN)

#### Timepoint

12 weeks after using topical imiquimod cream5%

#### Method of measurement

Loop Electrosurgical Excision Procedure and histological examination

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

Intervention group: the group receiving topical imiquimod 5%, for patients in the hospital, once a week with suitable study conditions and equipment, imiquimod cream 5% (250 mg) (Quimocyte® Cream 5% - Kimia Kala Razi Pharmaceutical Companyis) used in the transformation zone of the cervix for 12 weeks. .

#### Category

Treatment - Drugs

### 2

#### Description

Control group: Group receiving Loop Electrosurgical Excision procedure (LEEP)

#### Category

Treatment - Surgery

## Recruitment centers

### 1

#### Recruitment center

**Name of recruitment center**

Firoozgar Hospital

**Full name of responsible person**

Nooshin Sarikhani

**Street address**

Firoozgar Hospital, Beh afarin St, Karim khan Zand St,  
Valiasr Square

**City**

Tehran

**Province**

Tehran

**Postal code**

0000000000

**Phone**

+98 21 8214 1000

**Email**

nooshin\_wxw@yahoo.com

## Sponsors / Funding sources

### 1

#### Sponsor

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Reza Falak

**Street address**

Tehran, Hammet highway, Iran University of Medical  
Sciences

**City**

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**Postal code**

1445613131

**Phone**

+98 21 8670 2503

**Email**

Falak.r@iums.ac.ir

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Iran 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**

Iran University of Medical Sciences

**Full name of responsible person**

Nooshin Sarikhani

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

Tehran, Hammet highway, Iran University of Medical  
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## Person responsible for scientific inquiries

#### Contact

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Somaye Noeiteymoordash

**Position**

Assistant Professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Gynecology and Obstetrics

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## Person responsible for updating data

#### Contact

**Name of organization / entity**

Iran University of Medical Sciences

**Full name of responsible person**

Nooshin Sarikhani

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Gynecology and Obstetrics

**Street address**

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**Postal code**

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**Phone**

+98 21 8214 1000

**Email**

nooshin\_wxw@yahoo.com

**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**

Part of the data, such as information related to the main outcome or similar, can be shared.

**When the data will become available and for how long**

The access period starts 6 months after the results are published.

**To whom data/document is available**

It will be available for researchers working in academic and scientific institutions, and also people who are working in industry can apply for them.

**Under which criteria data/document could be used**

For use in research projects.

**From where data/document is obtainable**

Email to : nooshin\_wxw@yahoo.com

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

Sending an email and requesting information and waiting a few days to receive an email response.

**Comments**