Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

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

Protocol summary

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% Imquimod 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 cervical intraepithelial neoplasia

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
Tehran

Province
Tehran

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 Sciences

City
Tehran

Province
Tehran

Postal code
1445613131

Phone
+98 21 8670 2503

Email
nooshin_wxw@yahoo.com

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

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
noeiteymoordash.s@iums.ac.ir

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
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@yaho.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