Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of the effect of quaternary HPV vaccine in the treatment of women with cervical intraepithelial neoplasia cin1

Protocol summary

Study aim
Determining the effect of quadrivalent HPV vaccine in the treatment of women with cin1 cervical intraepithelial neoplasia

Design
Clinical trial with control group, single-blind, on 300 patients, block randomization

Settings and conduct
intervention in the obstetrics and gynecology clinic of Fatemieh Hospital, Hamedan University of Medical Sciences, in the scope of the study to investigate the effect of quadrivalent HPV vaccine Gardasil (Papilogard) in the treatment of women with cervical intraepithelial neoplasia cin1. The specialist who evaluates the patients is not aware of the treatment group or whether the person is placebo and the design will be done in a blinded manner.

Participants/Inclusion and exclusion criteria
Inclusion: age 21 to 45 years, not currently pregnant, not having had more than one sexual partner during their period, women with histologically confirmed CIN 1, undergoing conservative treatment. Exclusion: pregnancy, sensitivity to the vaccine, non-cooperation, those who have been cin 1 for more than 24 mont

Intervention groups
Intervention group: will receive conservative treatment according to ASCCP algorithm along with quadrivalent HPV vaccination (Gardasil). The vaccine will be administered as a series of intramuscular injections of 0.5 ml on day 1, month 2, and month 6. During 2 years, patients will be followed up. The efficacy of the HPV vaccine in the treatment of CIN 1 will be defined as a primary outcome. To measure this criterion, women are visited three times (12th, 18th , 24th) and undergo gynecological examination, pap smear test, colposcopy and annual biopsy. Control: Women in the control group will receive no HPV vaccination and placebo (vitamin B complex) according to the ASCCP algorithm.

Main outcome variables
Histological biopsy status of CIN 1 lesions in two control and intervention groups

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230522058253N2**
Registration date: **2023-10-26, 1402/08/04**
Registration timing: **registered_while_recruiting**

Last update: **2023-10-26, 1402/08/04**
Update count: **0**

Registration date
2023-10-26, 1402/08/04

Registrant information

Name
neda alimohammadi

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 81 3838 0808

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nalimohamadi68@yahoo.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2022-07-23, 1401/05/01

Expected recruitment end date
2024-07-22, 1403/05/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of the effect of quaternary HPV vaccine in the treatment of women with cervical intraepithelial neoplasia cin1

Public title
Evaluation of the effect of quaternary HPV vaccine in the treatment of women with cervical intraepithelial neoplasia cin1

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Age 21 to 45 years not currently pregnant not having had more than one sexual partner during their period received conservative treatment. women with histologically confirmed CIN 1
Exclusion criteria:
women who became pregnant received only one dose of the vaccine, or allergic to the vaccine Those who have been cin 1 for more than 24 month Those who do not participate in the study (non-cooperation) will be excluded from the study

Age
From **21 years** old to **45 years** old

Gender
Female

Phase
3

Groups that have been masked

- Care provider
- Outcome assessor

Sample size
Target sample size: **300**

Randomization (investigator's opinion)
Randomized

Randomization description
Patients will be counseled upon entering the hospital and informed consent will be obtained from the patient. After entering the room, they are examined and then they are randomly assigned to one of the two groups. Randomization is done by writing the letters A and B on two sheets and putting them in a box, and one of these sheets is taken out by the researcher for each patient. After finishing, the sheets are removed again for the next two patients with this random method until we reach the desired sample size.

Blinding (investigator's opinion)
Single blinded

Blinding description
The specialist who evaluates the patients is not aware of the treatment group or the person's placebo, and the design will be done in a blinded manner.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of hamadan University of Medical Sciences
Street address
Fatemieh hospital, Pastaran Ave.
City
hamadan
Province
Hamadan
Postal code
6517789971

Approval date
2022-07-23, 1401/05/01

Ethics committee reference number
IR.UMSHA.REC.1401.388

Health conditions studied

1

Description of health condition studied
Evaluation of the effect of quaternary HPV vaccine in the treatment of women with cervical intraepithelial neoplasia cin1 of Fatemiye Hospitan, Hamadan

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description
Histological biopsy status of CIN 1 lesions in two control and intervention groups

Timepoint
To measure this criterion, women are visited three times (months 12, 18,24) and undergo gynecological examination and pap smear test, colposcopy and annual biopsy and in 18 undergo gynecological examination and pap smear test (in case of pap smear test suspicious) have been placed.

Method of measurement
To measure this criterion, women are visited three times (months 12, 18, 24) and undergo gynecological examination and pap smear test, colposcopy and annual biopsy and in 18 undergo gynecological examination and pap smear test (in case of pap smear test suspicious) have been placed.

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Women in the intervention group will receive conservative treatment according to the ASCCP algorithm along with quadrivalent HPV vaccination (Gardasil). Gardasil targets HPV types 6, 11, 16 and 18. The vaccine will be administered as a series of intramuscular injections of 0.5 ml on day 1, month 2, and month 6. 48 to 72 hours after injection, patients will be examined for skin complications, fever, headache, pain and inflammation. During 2 years, patients will be followed up. The efficacy of the HPV vaccine in the treatment of CIN 1 will be defined as a primary outcome. To measure this criterion, women are visited three times (months 12, 18 ,24) and undergo gynecological examination and pap smear test, colposcopy and annual biopsy and in 18 24 undergo gynecological examination and pap smear test (in case of pap smear test suspicious) have been placed. At least two biopsy samples will be taken at the clinic. Colposcopy will be performed to evaluate the response to treatment despite the normal appearance of the cervix.

Category

Treatment - Drugs

2

Description

Control group: women in the control group will receive no HPV vaccination and placebo (vitamin B complex) according to the ASCCP algorithm. During 1.5 years, the patients will be followed up. The efficacy of the HPV vaccine in the treatment of CIN 1 will be defined as a primary outcome. To measure this criterion, women are visited three times (months 12, 18 ,24) and undergo gynecological examination and pap smear test, colposcopy and annual biopsy and in 18, 24 month undergo gynecological examination and pap smear test (in case of pap smear test suspicious) have been placed. At least two biopsy samples will be taken at the clinic. Colposcopy will be performed to evaluate the response to treatment despite the normal appearance of the cervix.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh Hospital

Full name of responsible person

Mehrangiz Zamanibonab

Street address

Pastaran Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Hamedan University of Medical Sciences

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?

No

Title of funding source

Hamadan 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

Hamedan University of Medical Sciences

Full name of responsible person

Mehrangiz Zamani bonab

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for scientific inquiries

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Hamedan University of Medical Sciences
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Position
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Specialist
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Person responsible for updating data

Contact
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Neda Alimohammadi
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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