

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jul 2026

Efficacy of HPV vaccine in preventing of increasing cervical lesion in abnormal Pap test

Protocol summary

Study aim

The aim of the study was to evaluate the efficacy of HPV vaccine in preventing of increasing cervical lesion in abnormal Pap test.

Design

This is a double-blind randomized controlled trial.

Settings and conduct

Between 2011-2015, 242 women between the ages of 22 to 50 years that suffering from various degrees of cervical lesions (CIN1, 2, 3) and referred to women's clinic affiliated to Shahid Sadoughi Hospital, Yazd, Iran, by signing a consent were studied to evaluate the effectiveness of HPV vaccine. Throughout the 2 years, all patients were treated according to the protocol; in addition, the results of the cervix inspections were documented. The collected data were analyzed using SPSS, chi-square, and fissure exact tests.

Participants/Inclusion and exclusion criteria

In this study, 242 women that had various grades of infection (CIN1, 2, 3) which referred to a women's clinic affiliated to Shahid Sadoughi University of Medical Sciences and Health Services for determining the effectiveness of HPV vaccine, by signing a consent were studied.

Intervention groups

In the intervention group, 138 women received HPV vaccinations. Throughout the 2 years, all patients were treated according to the protocol;

Main outcome variables

The main result of this study was to prevent increasing cervical lesion in an abnormal Pap test.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190603043801N1**

Registration date: **2019-07-24, 1398/05/02**

Registration timing: **retrospective**

Last update: **2019-07-24, 1398/05/02**

Update count: **0**

Registration date

2019-07-24, 1398/05/02

Registrant information

Name

mojgan Karimi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6435 2680

Email address

drkarimi2001@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2011-08-23, 1390/06/01

Expected recruitment end date

2015-11-21, 1394/08/30

Actual recruitment start date

2011-10-01, 1390/07/09

Actual recruitment end date

2015-11-01, 1394/08/10

Trial completion date

2015-11-01, 1394/08/10

Scientific title

Efficacy of HPV vaccine in preventing of increasing cervical lesion in abnormal Pap test

Public title

Efficacy of HPV vaccine in preventing of increasing cervical lesion

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

Women suffering from various degrees of cervical lesions (CIN 1, 2, 3)

Exclusion criteria:

Pregnant women Women with severe allergies

Age

From **22 years** old to **50 years** old

Gender

Female

Phase

3

Groups that have been masked

- Investigator
- Outcome assessor

Sample size

Target sample size: **242**

Actual sample size reached: **242**

Randomization (investigator's opinion)

Randomized

Randomization description

A randomized blocking method of four blocking was used using R statistical software.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study was a double-blinded study that investigator and outcome assessor were completely blinded.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

by Ethics Committee of the Yazd Shahid Sadoughi University of Medical Sciences

Street address

Yazd University of Medical Sciences, Yazd, Iran

City

Yazd

Province

Yazd

Postal code

8916189165

Approval date

2015-07-23, 1394/05/01

Ethics committee reference number

IR. IAU. YAZD. REC. 1394.008

Health conditions studied

1

Description of health condition studied

Cervical cancer

ICD-10 code

C51-C58

ICD-10 code description

Cervical cancer

Primary outcomes

1

Description

Clinical finding

Timepoint

At 1, 7, 12, 18, 24 months

Method of measurement

Gynecological examination

2

Description

Pap tests results

Timepoint

At 1, 7, 12, 24 months

Method of measurement

Pap smear Testing

Secondary outcomes

empty

Intervention groups

1

Description

In the Intervention group, women received three dosages of HPV vaccination.

Category

Treatment - Drugs

2

Description

In control group, women did not receive any dosages of HPV vaccination.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Gynecology clinic affiliated to Yazd University of Medical Sciences

Full name of responsible person

Mojgan Karimi Zarchi

Street address

Yazd University of Medical Sciences, Yazd, Iran

City

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Province

Yazd

Postal code

8916189165

Email

drkarimi2001@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Vice-Chancellor for Research and Technology

Street address

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+98 35 3724 0171

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info@ssu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yazd 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

Yazd University of Medical Sciences

Full name of responsible person

Mojgan Karimi -Zarchi

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Gynecology and Obstetrics

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Person responsible for scientific inquiries

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Full name of responsible person

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Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

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Position

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable