

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

A Phase III, Randomized, Two armed, Parallel, Double blinded, Active controlled Non-inferiority to evaluate the efficacy of Protection and safety of Papillomavirus vaccine (Bivalent, manufactured by Noyan Pajouhan Biopharma) in comparison with Cervarix® (Bivalent, manufactured by GlaxoSmithKline) in immunogenicity and GMT (Geometric Mean Titer) ratio in healthy female volunteers of 15 to 25 years of age.

Protocol summary

Study aim

Examine the non-inferiority and safety of papilloma virus vaccine (bi-valency, by Noyan Pajouhan Biopharma) in comparison with Cervarix® (Bivalency, by GlaxoSmithKline)

Design

Phase III, randomized, two arm, double blind, parallel, active controlled in 218 female subjects

Settings and conduct

Study will be conducted in Arash Women's hospital in Tehran. Study is double blinded (nurse, investigator and the volunteers), Information of investigational vaccine in a sealed envelope with continue number will be given to them.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Female subject of 15-25 years Being Healthy Subjects that have an intact uterus and cervix obtaining written informed consent Subjects who can and will comply with the requirements of the protocol.

Exclusion criteria: Previous vaccination against HPV. History of allergic reaction to vaccine administration. Chronic administration of immune-suppressants (more than 14 days) or other immune-modifying drugs within six months prior to the first vaccine dose. History of immunosuppressive or immunodeficient condition Known chronic diseases. Administration of immunoglobulin and/or any blood products within the 90 days before first dose of vaccine. Positive β -HCG test.

Intervention groups

This study has two arm in which one arm will receive the HPV vaccine 16,18 (Noyan Pajouhan Biopharma) and

other arm will receive the Cervarix® (GlaxoSmithKline) at a dose of 0.5 ml intramuscularly in 0,1,6 month schedule.

Main outcome variables

Primary outcome: Antibody titer against papillomavirus 16,18 with GMT comparison after 7 months. Secondary outcome: Proportion of local and systemic solicited and unsolicited events Proportion of serous adverse events Number of females with seroconversion against HPV 16,18 at the end of study.

General information

Reason for update

Acronym

HPV

IRCT registration information

IRCT registration number: **IRCT20090526001952N9**

Registration date: **2018-09-02, 1397/06/11**

Registration timing: **prospective**

Last update: **2019-09-01, 1398/06/10**

Update count: **3**

Registration date

2018-09-02, 1397/06/11

Registrant information

Name

Ashraf Moini

Name of organization / entity

Tehran University of Medical sciences

Country

Iran (Islamic Republic of)

Phone +98 21 7788 3283	Female
Email address hosp_arash@tums.ac.ir	Phase 3
Recruitment status Recruitment complete	Groups that have been masked • Participant • Care provider • Investigator • Outcome assessor • Data analyser
Funding source	
Expected recruitment start date 2019-07-06, 1398/04/15	Sample size Target sample size: 218
Expected recruitment end date 2019-10-07, 1398/07/15	Randomization (investigator's opinion) Randomized
Actual recruitment start date empty	Randomization description Randomization sequences will be made by R-CRAN software. This randomization sequence is consist of quadruple permuted balanced blocks to achieve the target sample size of 202 volunteers (made of 51 blocks that are only 202 sequences out of 204 sequences chain). Each of these sequences will be converted to untitled codes of alphabet and number. Centrally, master sheet of randomization will be kept with data manager team, therefor, after approval of eligibility of each volunteer, through phone call will be given to the site of study. Series of untitled codes and initial alphabets of volunteer's name and family name will make the identity number of volunteers for using in Case Report Form and made the information bank.
Actual recruitment end date empty	
Trial completion date empty	
Scientific title A Phase III, Randomized,Two armed, Parallel, Double blinded, Active controlled Non-inferiority to evaluate the efficacy of Protection and safety of Papillomavirus vaccine (Bivalent, manufactured by Noyan Pajouhan Biopharma) in comparison with Cervarix® (Bivalent, manufactured by GlaxoSmithKline) in immunogenicity and GMT (Geometric Mean Titer) ratio in healthy female volunteers of 15 to 25 years of age.	Blinding (investigator's opinion) Double blinded
Public title Evaluate non-inferiority efficacy of protection and safety of noyan pajouhan Biopharma human papillomavirus vaccine type 16,18 in healthy female volunteers.	Blinding description All the healthy volunteers will be vaccinated by an experienced nurse in the site of study and based on availability of vaccine in the stock and adhering the trial sticker on the vaccine and administration by nurse the nurse, investigator and the volunteers won't be aware of brand of administered vaccine, since in ICF aim of study has been mentioned, volunteers know that they will be randomly assigned in one of study vaccine groups and neither involved persons in the study nor volunteers are aware of type of administered vaccine. Randomization won't be disclosed to people who conduct the trial and the information in a sealed envelope with continue number will be given to them.
Purpose Prevention	Placebo Not used
Inclusion/Exclusion criteria Inclusion criteria: Female subjects between, and including, 15 to 25 years of age at the time of the first vaccination Healthy subjects as established by medical history and history-oriented clinical examination before entering into the study Subjects that have an intact uterus and cervix Written informed consent obtained from the subject prior to enrollment. Subjects who can and will comply with the requirements of the protocol. Exclusion criteria: Previous vaccination against HPV History of allergic reaction to vaccine administration Chronic administration of immune-suppressants (more than 14 days) or other immune-modifying drugs within six months prior to the first vaccine dose. Planned administration of a vaccine not foreseen by the study protocol. Any confirmed or suspected immunosuppressive or immunodeficient condition (based on medical history and physical examination). Known chronic disease such as Cancer, hepatic or renal disease, neurologic disease, diabetes or autoimmune diseases Administration of immunoglobulin and/or any blood products within the 90 days preceding the first dose of study vaccine Positive β -HCG test.	Assignment Parallel
Age From 15 years old to 25 years old	Other design features
Gender	Secondary Ids empty
	Ethics committees 1
	Ethics committee Name of ethics committee

Ethics committee of Tehran University of Medical Science

Street address

Vice-Chancellor in Research Affairs-Tehran University of Medical Science, 6th floor, near Qods st, keshavarz blvd.

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1417614418

Approval date

2018-07-31, 1397/05/09

Ethics committee reference number

IR.TUMS.VCR.REC.1397.321

Health conditions studied

1

Description of health condition studied

cervical cancer

ICD-10 code

C53

ICD-10 code description

Malignant neoplasm of cervix uteri

Primary outcomes

1

Description

Antibody titre against papillomavirus 16,18 with GMT comparison after 7 months.

Timepoint

After 7 months

Method of measurement

Geometric Mean Titre

Secondary outcomes

1

Description

Percentage of any adverse effects

Timepoint

Solicited adverse effects after one week of each injection; Unsolicited adverse effects after one month of each injection;

Method of measurement

Solicited, unsolicited and serious adverse event: ratio of events to total study population in percentage.

2

Description

Percentage of participants with seroconversion against HPV 16 and 18

Timepoint

Number of females with seroconversion after 6 months of first injection

Method of measurement

For seroconversion of type 16,18 Human papillomavirus measure the ratio of level of threshold of antibody against human papillomavirus 16,18 to total population in percentage.

Intervention groups

1

Description

Intervention group: Candidate vaccine: pre-filled vaccine syringe of HPV vaccine 16,18 (manufactured by Noyan Pajouhan Biopharma) 20 g HPV-16 L1 VLP/20 g HPV-18 L1 VLP intramuscular injection of (deltoid muscle non-dominant hand) 0.5 ml in 0,1,6 month schedule.

Category

Prevention

2

Description

Control group: Pre-filled vaccine syringe of HPV vaccine 16,18 (manufactured by GlaxoSmithKline) 20 g HPV-16 L1 VLP/20 g HPV-18 L1 VLP intramuscular injection of (deltoid muscle nondominant hand) 0.5 ml in 0,1,6 month schedule

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Arash Women's Hospital

Full name of responsible person

Ashraf Moini

Street address

Eastern 162th St.,Baghdarnia st.,Resalat Highway, Tehranpars, Tehran ,Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Noyan Pajouhan biopharma

Full name of responsible person
Maryam Aminipouya

Street address
No.421, # Science&Technology park, 16 st, North kargar St.

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Grant name

Grant code / Reference number

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

Title of funding source
Noyan Pajouhan biopharma

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Persons

Person responsible for general inquiries

Contact

Name of organization / entity
Arta zist pharmed

Full name of responsible person
Maryam Aminipouya

Position
Medical supervisor

Latest degree
Medical doctor

Other areas of specialty/work
Medical Pharmacy

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No.14, 4th floor, #55, shahin apartment, between Hemmat highway and atashneshan sq, North pajouhandeh, south Jennat abad.

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Person responsible for scientific inquiries

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Other areas of specialty/work
Gynecology and Obstetrics

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Person responsible for updating data

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Full name of responsible person
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Medical doctor

Other areas of specialty/work
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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

No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report

No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available