Clinical Trial Protocol
Iranian Registry of Clinical Trials

01 Jun 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 comparision after 7 months. Secondary outcome: Proportion of local and systemic solicited and unsolicited events Proportion of serous adverse events Number of females with seroconversin 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)

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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2019-07-06, 1398/04/15
Expected recruitment end date
2019-10-07, 1398/07/15
Actual recruitment start date
empty
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.

Public title
Evaluate non-inferiority efficacy of protection and safety of noyan pajouhan Biopharma human papillomavirus vaccine type 16,18 in healthy female volunteers.
Purpose
Prevention
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.
Age
From **15 years** old to **25 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **218**
Randomization (investigator's opinion)
Randomized
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.
Blinding (investigator's opinion)
Double blinded
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.
Placebo
Not used
Assignment
Parallel
Other design features

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.

City
Tehran

Province
Tehran

Postal code
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 nondominent 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 supervisior
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

Contact
Name of organization / entity
Tehran University of Medical Sciences
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Ashraf moini
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Professor of Arash women's Hospital
Latest degree
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Other areas of specialty/work
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Person responsible for updating data

Contact
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Latest degree
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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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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