Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Aug 2026

Investigation of the Immunogenicity and Safety of Lactococcus Lactis Vaccine Containing Codon-Optimized Full-Length E7 and E6 Oncoproteins of HPV-16 in Healthy Women

Protocol summary

Study aim

The Main Objective of This Study Was to Evaluate the Immunogenicity and Safety of Oral Vaccines Containing E7 and E6 Oncoproteins of Human Papillomavirous type 16, In Order to Eventually Use These Vaccines to Treat Cervical Cancer Caused by Human Papillomavirus type 16.

Design

One Hundred Sixty Healthy Iranian Non-Pregnant Volunteer Women Aged 18 to 59 Years Were Vaccinated at the Keyvan Virology Specialty Laboratory (KVSL). Upon Enrollment, Written Consent Was Obtained From Each Participant or Her Legal Guardian.

Settings and conduct

Keyvan Virology Specialty Laboratory

Participants/Inclusion and exclusion criteria

1- People Voluntarily Participate in the Research. 2- The Informed Consent Form Is Completed and Signed by the Person or Her companion. 3- Women PCR positive test for Papilloma Virus Infection. 4. Women Don't Have other sexually transmitted diseases. Women Don't be Pregnant 6. Women in Pap smear Test Don't Have Abnormal Conditions. 7. People Don't Have Other Cancerous Disease During the Course of Treatment. 8. Failure to Complete a Course of Treatment by Individuals Will Result in Their Exclusion from Study. 9- Getting Pregnant During the Course of Treatment Will Leave Women Out of Study.

Intervention groups

In This Study, There Are Six Target Groups That All Groups Are Identical in Terms of Health Standards, But Differ in Terms of Drug Use. This Will be Given to Three Groups (Test Groups) of the E7 and E6 Vaccine and Will be Given to the Following Three (Control Groups) Groups of Placebo.

Main outcome variables

Immunogenicity and Safety of Vaccines

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190504043464N1**
Registration date: **2019-05-19, 1398/02/29**
Registration timing: **retrospective**

Last update: **2019-05-19, 1398/02/29**
Update count: **0**

Registration date

2019-05-19, 1398/02/29

Registrant information

Name

Sedigheh Taghinezhad Saroukalaei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8854 9747

Email address

s.taghinezhad@srbiau.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-12-22, 1397/10/01

Expected recruitment end date

2019-02-09, 1397/11/20

Actual recruitment start date

2018-12-22, 1397/10/01

Actual recruitment end date

2019-02-19, 1397/11/30

Trial completion date

2019-02-20, 1397/12/01

Scientific title
Investigation of the Immunogenicity and Safety of Lactococcus Lactis Vaccine Containing Codon-Optimized Full-Length E7 and E6 Oncoproteins of HPV-16 in Healthy Women

Public title
Investigating of the Immunogenicity and Safety of Lactococcus Lactis Vaccine Related to Human Papillomavirus Type 16

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
1- People Voluntarily Participate in the Research. 2- The Informed Consent Form Is Completed and Signed by the Person or Her companion. 3- Women PCR positive test for Papilloma Virus Infection. 4. Women Don't Have other sexually transmitted diseases. Women Don't be Pregnant 6. Women in Pap smear Test Don't Have Abnormal Conditions.

Exclusion criteria:
1. People Don't Have Cancerous Disease During the Course of Treatment. 2. Failure to Complete a Course of Treatment by Individuals Will Result in Their Exclusion from Study. 3- Getting Pregnant During the Course of Treatment Will Leave Women Out of Study.

Age
From **18 years** old to **59 years** old

Gender
Female

Phase
1

Groups that have been masked

- Participant

Sample size
Target sample size: **200**
Actual sample size reached: **160**

Randomization (investigator's opinion)
Randomized

Randomization description
Volunteers Who Met eligibility Criteria Were Randomized Into Six Clinical Groups in a 2:1 Correlation Using Randomizer Software (Version 3.0) To Receive Four Rounds of Oral Vaccination using the E7 or E6 Vaccine or a Placebo at Weeks 1, 2, 4, and 8. Each Dose of Vaccine was Administered Orally, Once Each Morning After Fasting For Five Days, Each Treatment Week.

Blinding (investigator's opinion)
Single blinded

Blinding description
In This Study, Healthy Women Are Divided Into Six Groups. In This Phase, All Groups Are Treated and Simultaneously Given to Three Groups of Vaccines and Given to the Other Three Groups of Placebo.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Iran University of Medical Siences

Street address
Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran

City
Tehran

Province
Tehran

Postal code
۱۴۴۹۶۱۴۵۳۵

Approval date
2016-12-20, 1395/09/30

Ethics committee reference number
1395.95-04-30-29914

Health conditions studied

1

Description of health condition studied
Genital Wart

ICD-10 code
A63.0

ICD-10 code description
Anogenital (venereal) warts

Primary outcomes

1

Description
Change in Antibody and Interferon Levels

Timepoint
At the Beginning of the Study, 30, 60 and 90 Days After Taking the Vaccine.

Method of measurement
ELISA And ELISPOT KITS

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Volunteers Receive Four Rounds of Oral Vaccine (1 mL) at Weeks 1, 2, 4, and 8. Each Dose of Vaccine Was Administered Orally, Once Each Morning After Fasting For Five Days, Each Treatment Week. If No Side Effects Were Detected in Arms Given the Lower

Dose (10000000000 CFU/mL), the Dose Was Escalated to 50000000000 CFU/mL and 100000000000 CFU/mL.

Category

Treatment - Other

2

Description

Control group: Control Groups Receive Four Rounds of Placebo (1 mL) at Weeks 1, 2, 4, and 8. Each Dose of Placebo Was Administered Orally, Once Each Morning After Fasting For Five Days, Each Treatment Week. If No Side Effects Were Detected in Arms Given the Lower Dose (10000000000 CFU/mL), the Dose Was Escalated to 50000000000 CFU/mL and 100000000000 CFU/mL.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center
Keyvan Virology Specialty Laboratory

Full name of responsible person
Hossein Keyvani

Street address
Floor 1, Number 498, Beheshti Avenue

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Tehran

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keyvani.h@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Iran University of Medical Sciences

Full name of responsible person
Dr. Seyed Kazem Malakoti

Street address
Tehran, Hemmat Highway, next to Milad Tower, Iran University of Medical Sciences

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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
Iran University of Medical Sciences

Proportion provided by this source
50

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
Academic

Person responsible for general inquiries

Contact

Name of organization / entity
Islamic Azad University

Full name of responsible person
Amir Hossein Mohseni

Position
Researcher

Latest degree
Ph.D.

Other areas of specialty/work
Microbiology

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Person responsible for scientific inquiries

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Full name of responsible person
Sedigheh Taghinezhad Saroukalaei

Position
Researcher

Latest degree
Ph.D.

Other areas of specialty/work

Microbiology

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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