

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

02 Jul 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 Papillomavirus 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 Sciences

##### Street address

Iran University of Medical Sciences, Shahid Hemmat Highway, Tehran

##### City

Tehran

##### Province

Tehran

##### Postal code

۱۴۳۹۶۱۴۵۳۵

#### 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

**City**

Tehran

**Province**

Tehran

**Postal code**

1596983911

**Phone**

+98 21 8870 6556

**Fax**

+98 21 8870 6555

**Email**

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

**City**

Tehran

**Province**

Tehran

**Postal code**

1449614535

**Phone**

+98 21 86709

**Email**

s.taghinezhad@srbiau.ac.ir

**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

**Street address**

Floor 1, Number 498, Shahid Beheshti ave, Tehran.

**City**

Tehran

**Province**

Tehran

**Postal code**

1596983911

**Phone**

+98 21 8871 6556

**Fax**

+98 21 8871 6555

**Email**

amho.mohseni@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Islamic Azad University

**Full name of responsible person**

Sedigheh Taghinezhad Saroukalaei

**Position**

Researcher

**Latest degree**

Ph.D.

**Other areas of specialty/work**

Microbiology

**Street address**

Floor 1, No. 498, Shahid Beheshti Ave., Tehran.

**City**

Tehran

**Province**

Tehran

**Postal code**

1596983911

**Phone**

+98 21 8871 6556

**Fax**

+98 21 8871 6555

**Email**

taghinezhad.m@gmail.com

**Person responsible for updating data**

**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

**Street address**

Floor 1, No. 498, Shahid Beheshti Ave., Tehran.

**City**

Tehran

**Province**

Tehran

**Postal code**

1596983911

**Phone**

+98 21 8871 6556

**Fax**

+98 21 8871 6555

**Email**

amho.mohseni@gmail.com

**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