

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 2026

Investigating the effect of zinc nanoparticles on the transmission of HPV infection from a person infected with HPV virus

Protocol summary

Study aim

Investigating the effect of zinc nanoparticles on the transmission of HPV infection from a person infected with HPV virus

Design

A clinical trial with two patient groups, parallel treatment, balanced block randomization, and double-blind (The researcher and the participant). 70 patients were referred to Sinai Hospital.

Settings and conduct

In the group of this clinical trial at Sina Hospital in Tehran, Urology Research Centre, double-blind (patient and researcher) Weber balanced block randomization will be performed on 70 patients. Patients are divided into two groups: The first group, the Human papillomavirus sample, is taken 5 minutes after using the ointment containing zinc oxide nanoparticles. Second, the human papillomavirus sample will be taken 5 minutes after the local application of the placebo ointment on the wart (this ointment does not contain any nanoparticles and is used only to prevent the distorting effect in the study).

Participants/Inclusion and exclusion criteria

Inclusion criteria: Men between the ages of 18 and 60 who have obvious warts. Obtaining informed consent from patients. Exclusion criteria: People who have received the Gardasil vaccine according to the previous indications.

Intervention groups

Intervention group: human papillomavirus sample, 5 minutes after using ointment containing zinc nanoparticles. Control group: human papillomavirus sample, 5 minutes after topical application of placebo ointment on the wart (this ointment does not contain any nanoparticles and is used only to prevent the effect of confusion in the study).

Main outcome variables

Transmission of human papillomavirus

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190624043991N21**

Registration date: **2023-11-12, 1402/08/21**

Registration timing: **prospective**

Last update: **2023-11-12, 1402/08/21**

Update count: **0**

Registration date

2023-11-12, 1402/08/21

Registrant information

Name

Seyed Mohammad Kazem Aghamir

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-03-05, 1402/12/15

Expected recruitment end date

2025-03-05, 1403/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of zinc nanoparticles on the transmission of HPV infection from a person infected with HPV virus		Placebo Used
Public title Investigating the effect of zinc nanoparticles on the transmission of HPV infection		Assignment Parallel
Purpose Treatment		Other design features
Inclusion/Exclusion criteria Inclusion criteria: Men in the age range of 18 to 60 years who have prominent genital warts Obtaining informed consent from patients Exclusion criteria: Men who have received the Gardasil vaccine according to the previous indications		Secondary Ids empty
Age From 18 years old to 60 years old		Ethics committees 1
Gender Male		Ethics committee Name of ethics committee Ethics Committees in Medical Medical Research
Phase 3		Street address Room 604, Sixth Floor, Central Staff Building, Tehran University of Medical Sciences, Tehran, Iran
Groups that have been masked • Participant • Investigator		City Tehran
Sample size Target sample size: 70		Province Tehran
Randomization (investigator's opinion) Randomized		Postal code 1417653761
Randomization description For randomization, the balanced block randomization method is used to generate blocks with size of 4. Intervention group A and control group B have been determined. According to the randomization method, we expect the two groups to differ by a maximum of 2 people in terms of the number of people assigned. After the methodologist prepares the randomization sequence using the Sealdenvelop online site, the generated sequence will be available to a technician outside the research team. blocks (A or B) are placed in envelopes. After the arrival of the first patient with the inclusion criteria, the envelopes are randomly selected, and the type of patient group is informed to the research team through a trained technician. Based on the randomly selected envelope, the patient is placed in the group (Double G plus placebo: 30 patients) or (Double G plus theophylline: 30 patients).		Approval date 2023-05-22, 1402/03/01
Blinding (investigator's opinion) Double blinded		Ethics committee reference number IR.TUMS.MEDICINE.REC.1402.107
Blinding description The present study is a double-blind, randomized clinical trial. The researcher and the participant will not know about the randomization method. The present study is a double-blind, randomized clinical trial study. The researcher and the participant will not know how to be placed in the control or intervention groups. In both groups, the same ointment made by Bonyakhte company is used. The first group is an ointment containing zinc oxide nanoparticles , The Second group is a placebo ointment that does not contain any nanoparticles.		Health conditions studied 1 Description of health condition studied Genital warts in the genitals of men ICD-10 code A63.0 ICD-10 code description Anogenital (venereal) warts
		Primary outcomes 1 Description The use of zinc oxide nanoparticles on HPV transmission Timepoint Before and 5 minutes after topical application of the ointment Method of measurement Molecular diagnosis laboratory (Real Time PCR)
		Secondary outcomes empty
		Intervention groups

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Description

Intervention group: Sample of human papillomavirus, 5 minutes after using the ointment containing zinc oxide nanoparticles, 25% (every 100 grams contains 25 groups of drugs), Bonyakhte Technology Company, use it once on the wart and then take a sample.

Category

Treatment - Drugs

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Description

Control group: human papillomavirus sample, 5 minutes after topical application of placebo ointment on the wart (Vaseline ointment that does not contain any nanoparticles and is used only to avoid the confounding effect in the study), Bonyakhte Technology Company, use it once on the wart and then take a sample.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Dr Mohammad Kazem Aghamir

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Urology Research Center, Sina Hospital, Imam Khomeini St., Tehran, Iran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Dr. Akbar Fotouhi

Street address

Sixth Floor, Central University, Quds Ave., Keshavarz Boulevard, Tehran, Iran.

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Dr Akram Mirzaei

Position

Researcher

Latest degree

Ph.D.

Other areas of specialty/work

Medical Biology

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Full name of responsible person

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Position

Head of Urology Research Center

Latest degree

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

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

Title and more details about the data/document

Demographic information anonymously

When the data will become available and for how long

One year after publication

To whom data/document is available

Researchers working in academia, physicians, surgeons and hospitals

Under which criteria data/document could be used

Any analysis can be done with the consent of the main researcher

From where data/document is obtainable

Sina Hospital, Urology Research Center, Head of Urology Research Center: Dr. Seyed Mohammad Kazem Aghamir 00982166348560 mkaghamir@tums.ac.ir

What processes are involved for a request to access data/document

After reviewing the information by the administrator and epidemiologist, the patient information will be available for the applicant by the provision of a patient's privacy.

Comments