# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

27 Sep 2026

## The effect of curcumin on the clearance of human papillomavirus infection and the diagnostic quality of cervical smear in patients with high-risk human papillomavirus

## Protocol summary

**Study aim**
Determining the effect of curcumin on the clearance of human papillomavirus infection and the diagnostic quality of cervical smear

**Design**
Clinical trial with control group, double-blind, randomized, phase 3 on 90 patients. Excel software rand function was used for randomization.

**Settings and conduct**
Women between the ages of 30 and 65 who have been referred for Pap smear screening and then have been asked for HPV typing and reported a "high risk" outcome will be invited to enter the study based on inclusion and exclusion criteria. Admission of patients to the study will be available and easy, but their allocation in two groups of intervention or placebo will be done by simple random assignment with the help of a computer. In the intervention group, patients treated with cinacurcumin 40 are given orally once daily for 6 months. In the control group, patients will be treated routinely. Groups will be given dietary recommendations. Location: Taleghani Hospital, Arak University of Medical Sciences

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Women with high-risk Pap smear and HPV results; Age 30 to 65 years, no candidiasis or candidiasis vaginitis, trichomoniasis, and other infections; no known immunodeficiency or autoimmune disease; HIV-positive patients; no long-term use of corticosteroids or immunosuppressants; no smoking; no pregnancy; no CIN2 or CIN3 in cervical biopsy. Exclusion criteria: Patient dissatisfaction with participation in the project.

**Intervention groups**
In the intervention group of cinacurcumin 40 one oral drug of Sina drug will be prescribed daily for 6 months. Control group, placebo (capsules similar to the main drug to be purchased from the company, Will receive routine treatment.

**Main outcome variables**
The main measurable outcome is HPV and Pap smears, and other outcomes include lesion size, patients' clinical signs, and drug side effects.

## General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20220629055314N1**
Registration date: **2022-07-20, 1401/04/29**
Registration timing: **prospective**

Last update: **2022-07-20, 1401/04/29**
Update count: **0**

**Registration date**
2022-07-20, 1401/04/29

**Registrant information**

**Name**
maryam mohsenikia

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2022-07-23, 1401/05/01

**Expected recruitment end date**
2022-09-23, 1401/07/01

**Actual recruitment start date**
empty
**Actual recruitment end date**
empty
**Trial completion date**
empty

**Scientific title**
The effect of curcumin on the clearance of human papillomavirus infection and the diagnostic quality of cervical smear in patients with high-risk human papillomavirus

**Public title**
The effect of curcumin on the treatment of human papillomavirus infection
**Purpose**
Treatment
**Inclusion/Exclusion criteria**
**Inclusion criteria:**
Women with high-risk Pap smear and HPV results Age 30 to 65 years
**Exclusion criteria:**
Known immune deficiency or autoimmune disease HIV positive patients Long-term use of corticosteroids or immunosuppressants smoking Pregnancy Infection with CIN2 or CIN3 in cervical biopsy Use of anticoagulants such as heparin, aspirin, clopidogrel, dipyridamole, warfarin and ticlopidine History of allergies to turmeric or other drugs, foods and dyes Gallbladder stones or bile duct obstruction and diseases related to gastric acidosis or active gastrointestinal ulcers Candida, trichomoniasis, and other infections of the cervix or vaginitis
**Age**
From **30 years** old to **65 years** old
**Gender**
Female

**Phase**
3
**Groups that have been masked**

- Participant
- Investigator
- Outcome assessor
- Data analyser

**Sample size**
Target sample size: **90**
**Randomization (investigator's opinion)**
Randomized
**Randomization description**
Both patients and all patient-related researchers will be unaware of receiving cinacurcumin or routine treatment. All women who are to be included in the study are coded, and the encrypted computer file shows what each code means, only if the person's health is compromised. Block randomization method will be used to assign eligible people to two groups. The size of the blocks is 4 and 6. Randomization will be done individually. In the block method, due to the use of different combinations in each block, it is not possible to predict the randomization sequence, so the concealment process will also be followed. To guarantee the concealment process, the generated randomization sequence will be extracted as an Excel file and will remain with the epidemiologist's colleague, then to allocate the eligible people to two groups, the sick person will contact the epidemiologist and for the status of each person's placement in the groups, A decision will be made according to the randomization sequence. The online program available on the Sealed Envelope website will be used to generate the block randomization sequence.
**Blinding (investigator's opinion)**
Double blinded
**Blinding description**
All patients and researchers (responsible for data collection, responsible for follow-up and evaluation of results) are unaware of the content of the received drug and the drug is coded. A placebo will be used for blinding. Both groups will receive routine treatments. In addition to routine treatment, one group will receive curcumin and one placebo group. The packages are completely similar and unique codes will be attached to each package. Therefore, patients, researchers and statistical analysts will be unaware of the allocation of people to two groups. The codes will also be kept with the epidemiologist colleague until the codes will be opened at the end of the study.
**Placebo**
Used
**Assignment**
Other
**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**
**Name of ethics committee**
Ethics Committee of Arak University of Medical Sciences
**Street address**
emam khomini blv, taleghani hospital
**City**
arak
**Province**
Markazi
**Postal code**
3814115091
**Approval date**
2022-05-22, 1401/03/01
**Ethics committee reference number**
IR.ARAKMU.REC.1401.076

## Health conditions studied

### 1

**Description of health condition studied**
Cervical human papilloma virus infection

**ICD-10 code**
**ICD-10 code description**

## Primary outcomes

**1**

**Description**
Clearance of human papillomavirus infection from the cervix
**Timepoint**
Before the intervention and 6 months later
**Method of measurement**
Detection and Typing of Human Papilloma Virus by PCR

**2**

**Description**
Diagnostic quality of cervical smear
**Timepoint**
Before the intervention and 6 months later
**Method of measurement**
Pap smear sampling from the cervix

## Secondary outcomes

empty

## Intervention groups

**1**

**Description**
Intervention group: Sinacurcumin 40 (each capsule contains 40 mg of nanomicelle curcumin) orally once a day for 6 months.
**Category**
Treatment - Drugs

**2**

**Description**
Control group: They will receive placebo for six months, which they will consume orally for six months
**Category**
Placebo

## Recruitment centers

**1**

**Recruitment center**
**Name of recruitment center**
Kowsar Clinic, Taleghani Hospital, Arak University of Medical Sciences
**Full name of responsible person**
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## Sponsors / Funding sources

**1**

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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**
Arak 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**
Arak University of Medical Sciences
**Full name of responsible person**
maryam mohsenikia
**Position**
resident
**Latest degree**
Medical doctor
**Other areas of specialty/work**
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## Person responsible for scientific inquiries

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## Person responsible for updating data

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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**
Yes - There is a plan to make this available

**Data Dictionary**
Yes - There is a plan to make this available

**Title and more details about the data/document**
The data related to the evaluation after taking the drug and the evaluation before the intervention will be accessible anonymously

**When the data will become available and for how long**
Data will be available one month after the article is published

**To whom data/document is available**
All medical researchers working in scientific and academic research centers

**Under which criteria data/document could be used**
Documents will be made available to the applicant if needed for a detailed review or supplementary idea about the project.

**From where data/document is obtainable**
Arak University of Medical Sciences Vice Chancellor for Research and Technology

**What processes are involved for a request to access data/document**
After a written request to the Vice Chancellor for Research of the University of Medical Sciences, if the university approves, the documents will be available to the applicant, which may take between one and two months.

**Comments**