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
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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
maryam mohsenikia
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Sponsors / Funding sources

1

Sponsor
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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
Gynecology and Obstetrics
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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