# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

01 Jun 2026

## Comparing the effectiveness of 5% 5-fluorouracil ointment and 50 microgram calcipotriol ointment in the treatment of genital warts

### Protocol summary

**Study aim**
Comparison of the effectiveness of 5-fluorouracil ointment 5% and calcipotriol ointment 50 micrograms in the treatment of genital warts

**Design**
A clinical trial without a control group, community-based and practice-oriented, parallel groups, double-blind, randomized, phase 2 on 60 patients (30 people receiving 5-fluorouracil 5% and 30 people receiving calcipotriol 50 micrograms) . A simple randomization method was used for randomization.

**Settings and conduct**
To investigate the effectiveness of 5% 5-fluorouracil ointment in genital warts and compare its effect with calcipotriol 50 micrograms, patients diagnosed with genital warts who refer to the skin clinic of Imam Khomeini Hospital, Ahvaz, are randomly divided into two groups. The first group will receive 5% 5-fluorouracil ointment and the second group will receive 50 micrograms of calcipotriol. Then, after 1 month of treatment, the effect of the drug is measured through a clinical examination. Also, the study is conducted in a double-blind manner (patient and interventionist) so that the medicine in the same container will be given to the patients by a non-interventionist.

**Participants/Inclusion and exclusion criteria**
Inclusion criteria: Patients who are diagnosed with genital warts for the first time or who have not received genital warts treatment in the last three months, and do not have any other skin disease. Exclusion criteria: patients with immune system dysfunction, with a previous history of allergy to the study drugs, and pregnant and lactating women.

**Intervention groups**
Receiving 5% 5-fluorouracil ointment (n=30) and calcipotriol ointment 50 micrograms (n=30) three times a week for one month

**Main outcome variables**
The location and size of the lesion, and the number of genital warts

### General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20230913059421N1**
Registration date: **2023-10-01, 1402/07/09**
Registration timing: **prospective**

Last update: **2023-10-01, 1402/07/09**
Update count: **0**

**Registration date**
2023-10-01, 1402/07/09

**Registrant information**

**Name**
Ahmadreza Zamani

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 916 601 7804

**Email address**
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**Recruitment status**
**Recruitment complete**

**Funding source**

**Expected recruitment start date**
2023-10-07, 1402/07/15

**Expected recruitment end date**
2024-01-05, 1402/10/15

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**

empty

**Scientific title**
Comparing the effectiveness of 5% 5-fluorouracil ointment and 50 microgram calcipotriol ointment in the treatment of genital warts

**Public title**
Effectiveness of 5% fluorouracil ointment in the treatment of genital warts

**Purpose**
Treatment

**Inclusion/Exclusion criteria**

**Inclusion criteria:**
Patients who are diagnosed with genital warts for the first time or who have not received treatment for genital warts in the last three months. Do not have any other skin disease

**Exclusion criteria:**
Patients with immune system dysfunction Having a previous history of allergy to the studied drugs Pregnant and lactating women

**Age**
From **18 years** old

**Gender**
Both

**Phase**
2

**Groups that have been masked**

- Participant
- Care provider
- Investigator
- Outcome assessor

**Sample size**
Target sample size: **60**

**Randomization (investigator's opinion)**
Randomized

**Randomization description**
Patients are randomly assigned to two intervention groups using randomized block method. For this purpose, blocks of four are prepared, the name of the intervention is written on two sheets and the name of the comparison is written on the other two sheets. The sheets are piled up and placed in the container, and one sheet is pulled out for each patient without placing it. Then four sheets are returned to the container and this process is repeated until the sample volume is reached.

**Blinding (investigator's opinion)**
Double blinded

**Blinding description**
Patients will be evaluated by another specialist as part of the main research, and the design will be done in a double-blind manner. Medicines are provided to patients in a sealed container which is the same for two groups by a person who does not participate in this study and the patients will not know about its contents due to the similarity of the two types of medicine.

**Placebo**
Not used

**Assignment**
Parallel

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**
Ethics Committee of Jundishapur Ahvaz University of Medical Sciences

**Street address**
Golestan

**City**
Ahvaz

**Province**
Khouzestan

**Postal code**
6441945781

**Approval date**
2023-05-30, 1402/03/09

**Ethics committee reference number**
IR.AJUMS.HGOLESTAN.REC.1402.044

## Health conditions studied

### 1

**Description of health condition studied**
Genital wart

**ICD-10 code**
B07

**ICD-10 code description**
Viral warts

## Primary outcomes

### 1

**Description**
location of the lesion

**Timepoint**
Before treatment, 1 and 3 months after treatment

**Method of measurement**
Physical examination

### 2

**Description**
The size of the lesion

**Timepoint**
Before treatment, 1 and 3 months after treatment

**Method of measurement**
Physical examination

### 3

**Description**
Number of genital warts

**Timepoint**
Before treatment, 1 and 3 months after treatment
**Method of measurement**
Physical examination

## Secondary outcomes

### 1

**Description**
Recurrence of the disease
**Timepoint**
Before treatment, 1 and 3 months after treatment
**Method of measurement**
Physical examination

### 2

**Description**
Side effects
**Timepoint**
1 and 3 months after treatment
**Method of measurement**
Physical examination

## Intervention groups

### 1

**Description**
Intervention group: Recipient of topical 5-FU 5% ointment (Efudex Co) three times a week (n=30) for one month
**Category**
Treatment - Other

### 2

**Description**
Intervention group: Receiving topical calcipotriol ointment (Tehran Chemie Pharmaceutical Co) twice a day (n=30) for one month
**Category**
Treatment - Other

## Recruitment centers

### 1

**Recruitment center**
**Name of recruitment center**
Dermatology Clinic of Imam Khomeini Hospital
**Full name of responsible person**
Ahmadreza Zmani
**Street address**
Golestan
**City**
Ahvaz
**Province**
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## Sponsors / Funding sources

### 1

**Sponsor**
**Name of organization / entity**
Ahvaz University of Medical Sciences
**Full name of responsible person**
Mehrnoosh Zakerkish
**Street address**
Golestan
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zakerkish-m@ajums.ac.ir
**Grant name**
**Grant code / Reference number**
**Is the source of funding the same sponsor organization/entity?**
Yes
**Title of funding source**
Ahvaz 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**
Ahvaz University of Medical Sciences
**Full name of responsible person**
Ahmadreza Zamani
**Position**
Resident
**Latest degree**
Medical doctor
**Other areas of specialty/work**
Dermatology
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## Person responsible for updating data

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**
No - There is not a plan to make this available
**Justification/reason for indecision/not sharing IPD**
There is no further information
**Study Protocol**
Undecided - It is not yet known if there will be a plan to make this available
**Statistical Analysis Plan**
Not applicable
**Informed Consent Form**
Undecided - It is not yet known if there will be a plan to make this available
**Clinical Study Report**
Not applicable
**Analytic Code**
Not applicable
**Data Dictionary**
Not applicable