

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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	Other design features
Scientific title Comparing the effectiveness of 5% 5-fluorouracil ointment and 50 microgram calcipotriol ointment in the treatment of genital warts	Secondary Ids empty
Public title Effectiveness of 5% fluorouracil ointment in the treatment of genital warts	Ethics committees
Purpose Treatment	1
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	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
Age From 18 years old	Approval date 2023-05-30, 1402/03/09
Gender Both	Ethics committee reference number IR.AJUMS.HGOLESTAN.REC.1402.044
Phase 2	Health conditions studied
Groups that have been masked • Participant • Care provider • Investigator • Outcome assessor	1 Description of health condition studied Genital wart ICD-10 code B07 ICD-10 code description Viral warts
Sample size Target sample size: 60	Primary outcomes
Randomization (investigator's opinion) Randomized	1 Description location of the lesion Timepoint Before treatment, 1 and 3 months after treatment Method of measurement Physical examination
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.	2 Description The size of the lesion Timepoint Before treatment, 1 and 3 months after treatment Method of measurement Physical examination
Blinding (investigator's opinion) Double blinded	3 Description Number of genital warts
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	

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

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Golestan

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Ahvaz University of Medical Sciences

Full name of responsible person

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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

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 scientific inquiries

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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