Clinical Trial Protocol
Iranian Registry of Clinical Trials

28 Jul 2026

Evaluation of the efficacy and safety of ((WartOver)) topical ointment for the treatment of cutaneous warts: a randomized triple-blind clinical trial

Protocol summary

Study aim
Investigating the efficacy and safety of WartOver ointment in the treatment of cutaneous warts

Design
Randomized, parallel, three-blind, superiority clinical trial to investigate the safety and efficacy of wart-over ointment (palm extract) compared to placebo in patients with skin warts.

Settings and conduct
The study will be conducted in patients referred to the Center for Education and Research of Skin Diseases and Leprosy, Dermatology Clinic of Imam Khomeini and Shohadaye Tajrish Hospital. Patients are randomly divided into drug and placebo groups. The patient, doctor and analysist are blinded. Patients use the ointment on the lesion at least twice a day for a maximum of 12 weeks and have monthly visit until wart complete removal. If less than 20% of the wart area is removed after 8 weeks, the patient will be excluded. lesion Photographs are taken at baseline and each visit. 1 month after lesion complete removal, the patient will be re-visited in terms of recurrence.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Age between 18 to 65 years The presence of up to 5 skin warts with an area of up to 1 cm 4 weeks have passed since other treatments such as cryotherapy and... Exclusion criteria: History of cutaneous malignancy and premalignancy, immunodeficiency and immunosuppressant drug use, Genital lesions, eyelid involvement, complicated infection Receipt of any human papillomavirus vaccine within 6 months prior to study

Intervention groups
"Wart Over" ointment consisting of 10% methanol extract of palm, which should be used on the lesion at least 2 times a day for a maximum of 12 weeks. Placebo: Ointment without palm methanol extract and similar in color and smell, which should be used on the lesion at least 2 times a day for a maximum of 12 weeks.

Main outcome variables
Assessment of complete removal of target cutaneous wart during 12 weeks (or less) after treatment.

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20200509047352N2**
Registration date: **2023-01-27, 1401/11/07**
Registration timing: **prospective**

Last update: **2023-01-27, 1401/11/07**
Update count: **0**

Registration date
2023-01-27, 1401/11/07

Registrant information
Name
Azin Ayatollahi
Name of organization / entity
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Iran (Islamic Republic of)
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Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2023-02-04, 1401/11/15
Expected recruitment end date
2023-09-06, 1402/06/15
Actual recruitment start date
empty
Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the efficacy and safety of ((WartOver)) topical ointment for the treatment of cutaneous warts: a randomized triple-blind clinical trial

Public title

Investigating the effect of ((WartOver)) ointment in the treatment of skin warts

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Over 18 years of age The participant is able to understand the conditions and instructions of the clinical trial The presence of up to 5 skin warts with an area of up to 1 cm Presence of the lesion at least 4 weeks in the baseline visit At least 4 weeks have passed since other treatments such as cryotherapy and... Willing to sign an informed consent to participate in this study

Exclusion criteria:

Pregnancy and lactation history of skin malignancy and premalignancy (eg, actinic keratosis) immunodeficiency (eg, due to chemotherapy, glucocorticoids, systemic steroids, genetic immunodeficiency, transplant status, AIDS, etc.) lesions in the genital area eyelid involvement complicated infection receipt of any human papillomavirus (HPV) vaccine within 6 months of enrollment any current skin disease or systemic disease (eg, psoriasis, atopic dermatitis, eczema, sun damage) or condition that, in the opinion of the researcher, participating in the study may expose the participant to unnecessary risk or interfere with the conduct of the study or evaluations, such as sunburn, excessive hair, open wounds.

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization by Minimization will be used to allocate participants to one of the two treatment or vehicle arms. For this purpose, we will use MinimPy version 2.0 software. In this software, the minimization and reduction of the differences between the two arms are accomplished by specifying covariates that are likely to play a role in the prognosis of the disease and by using the marginal imbalance calculation by the software. covariates include age, gender, duration of cutaneous warts, number of warts in each patient, history of treatment, location, and type of warts.

Blinding (investigator's opinion)

Triple blinded

Blinding description

None of the participants, researchers, trial administrators, other health care personnel (doctors, nurses, etc.) who are responsible for the care of the patients, data collectors, and outcomes evaluators will be aware of the allocation of patients to the two groups under study. To apply blinding in this trial, the similarities between the interventions in the two study treatment groups are predicted. Therefore, the placebo will be produced in similar packages, with similar physical properties (in terms of color, smell, appearance, etc.). The amount of consumption and the number of times of consumption were the same in both products. The only difference between these two products would be the code A or B inserted on the respective package and box by the designated pharmacist. Others will be unaware of the nature of these two products and the codes mentioned in them. Due to the real-time allocation of participants in MinimPy software, as well as the presence of a random component in the allocation algorithm of this software, in addition to obtaining two arms that are as similar as possible, Allocation Concealment would also implement properly. In this way, in addition to blinding the participants and personnel of the clinical study (in order to prevent performance bias), it is possible to ensure the blinding of the result evaluation (in order to prevent detection bias) and to conduct the study in a triple-blind manner. At the end of the analyses of the results, codes will be broken and the nature of both groups would be determined.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Research Ethics Committees of School of Medicine-Tehran University of Medical Sciences

Street address

Office of Research Vice-Chancellor, Faculty of Medicine Building No. 1, Tehran University of Medical Sciences, Porsina St.,Qods St., Enqelab St., Tehran

City

Tehran

Province
Tehran
Postal code
1598718311
Approval date
2022-08-30, 1401/06/08
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1401.416

Health conditions studied

1

Description of health condition studied
Cutaneous Warts
ICD-10 code
B07
ICD-10 code description
Viral warts

Primary outcomes

1

Description
Number of patients with complete removal of target cutaneous wart dusing 12 weeks (or less) after treatment.
Timepoint
Before initial of treatment and then every month after starting to use wart-over ointment (with palm extract) or placebo until the skin wart is completely removed, the lesion is photographed. The treatment lasts up to 12 weeks.
Method of measurement
Reduction of the wart area or its complete removal will be evaluated by the digital lesion photos which are taken before the start of the treatment and then at each visit (monthly) and for a maximum period of 12 weeks, by Image-j software.

Secondary outcomes

1

Description
The percentage of skin wart area change during maximum 12 weeks
Timepoint
Before initial of treatment and then every month after starting to use wart-over ointment (with palm extract) or placebo until the skin wart is completely removed, the lesion is photographed. The treatment lasts up to 12 weeks.
Method of measurement
Reduction of the wart area or its complete removal will be evaluated by the digital lesion photos which are taken before the start of the treatment and then at each visit (monthly) and for a maximum period of 12 weeks, by Image-j software.

2

Description
Investigating of patients' satisfaction with the treatment
Timepoint
At the beginning of the study and before the start of the intervention and then the end of the treatment period if the wart is completely removed or the end of the 12th week if the area of the wart is reduced
Method of measurement
Give score with using a five-point scale (one = very dissatisfied, five = very satisfied)

3

Description
Investigating the treatment period required for the complete clearance of cutaneous warts with "WartOver" topical ointment
Timepoint
The Assessment of treatment period required for the complete clearance of cutaneous warts with "WartOver" topical ointment would be conducted in the group receiving ((WartOver)) topical ointment after the completion of treatment (in the 12th week or in the last visit in which the researcher determines complete clearance).
Method of measurement
In participants who will achieve partial or complete clearance of cutaneous warts with the use of ointment, the duration of treatment will be recorded and reported.

4

Description
Investigating the recurrence of cutaneous warts in case of complete removal
Timepoint
One and three months after the complete removal of the cutaneous wart and discontinuing treatment
Method of measurement
Face-to-face visit and examination of the treated area

5

Description
Investigation of side effect
Timepoint
Side effect investigation during the use of the ointment for a maximum of 12 weeks
Method of measurement
In case of occurrence, side effects are recorded in the case report form in each visit (monthly) and also patients can report adverse effects anytime according to the contact number provided to them.

Intervention groups

1

Description
Intervention group: Wart Over ointment consists of 10% methanol extract of palm and Isopropyl cera alba (White

wax), White petrolatum, Myristate, Propylene glycol palmitostearate and Oleyl alcohol, which is manufactured by Aram Aras Pishdad Azma pharmaceutical company for the treatment of skin warts. The ointment should be used at least 2 times a day on the target site until the wart is completely removed or for a maximum of 12 weeks.

Category

Treatment - Drugs

2

Description

Control group: placebo ointment does not contain palm methanolic extract, but other compounds such as Isopropyl cera alba (White wax), White petrolatum, Myristate, Propylene glycol palmitostearate, and Oleyl alcohol are presence in the formulation. Placebo is manufatured by Aram Aras Pishdad Azma pharmaceutical company for the clinical trial of skin warts and it is completely similar to the drug in terms of color and smell. The ointment should be used at least 2 times a day on the target site until the wart is completely removed or for a maximum of 12 weeks.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Center for Research and Training in Skin Diseases And Leprosy -Tehran University of Medical Science

Full name of responsible person

Azin Ayatollahi

Street address

Skin Diseases and Leprosy Research and Education Center, No. 415, corner of Naderi St. (former Sohail), Shahid Taleghani St., Tehran

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Province

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Phone

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Email

dermalab@tums.ac.ir

Web page address

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2

Recruitment center

Name of recruitment center

Dermatology clinic in Imam Khomeini hospital

Full name of responsible person

Safoura Shakoeinejad

Street address

Imam Khomeini Hospital Complex, Dr. Gharib Street, at the end of Keshavarz Boulevard, Tehran

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Phone

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Email

Imamhospital@tums.ac.ir

3

Recruitment center

Name of recruitment center

Shohadaye Tajrish Hospital

Full name of responsible person

Reza Mahmoud Robati

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Shohadaye Tajrish hospital, Shohadaye Tajrish Square, Tehran

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Azin Ayatollahi

Street address

The Center for Research and Training in Skin Diseases and Leprosy, No. 415, Naderi St., Taleghani Ave., Tehran, Iran

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source
Aram pishdad aras azma Ltd.

Proportion provided by this source
100

Public or private sector
Private

Domestic or foreign origin
Domestic

Category of foreign source of funding
empty

Country of origin

Type of organization providing the funding
Industry

Person responsible for general inquiries

Contact

Name of organization / entity
Tehran University of Medical Sciences

Full name of responsible person
Azin Ayatollahi

Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Dermatology

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Contact

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Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Dermatology

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Full name of responsible person
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Position
Assistant Professor

Latest degree
Specialist

Other areas of specialty/work
Dermatology

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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
Due to confidentiality

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available