Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The effect of green tea extract (sincathecin) in the treatment of patients with common and palmoplantar warts referred to the dermatology clinic of Imam Reza Hospital in Mashhad and its comparison with the control group

Protocol summary

Study aim

Evaluation of the effect of green tea extract (Sinecatechins) in the treatment of common warts (palmoplantar) and its comparison with cryotherapy

Design

The clinical trial has an intervention group and a control group in parallel, one-way, blinded, randomized, on 80 patients, which uses the envelope method for randomization.

Settings and conduct

This study is performed in the dermatology clinic of Imam Reza Hospital in Mashhad, Khorasan Razavi Province, Iran. During the initial visit, the patients' demographic information, previous records, are examined and examinations are performed, and the size, shape, number and location of the lesions are recorded, and photographs of the lesions are taken. During the treatment period, patients are visited every month and their lesions will be evaluated by photographing and comparing with the initial recorded images. Also, once every two weeks, patients are evaluated for drug side effects and local sensitivity. Treatment of the cured patients is stopped and they will be visited again one and three months later to check for possible recurrence.

Participants/Inclusion and exclusion criteria

Patients referred to the dermatology clinic of Imam Reza Hospital, who have at least one normal non-genital wart of both men and women, who are 15 to 35 years old and are otherwise healthy, are included in the study. People with underlying disease, immunodeficiency, and pregnant and lactating people, as well as people with a history of skin disease or allergy to a specific topical or systemic drug, will not be included in the study.

Intervention groups

The intervention group was treated topically with green tea extract containing 15% Sinecatechins three times a day for 8 hours for 16 weeks. For the control group, cryotherapy is performed every two weeks until complete healing of the lesions.

Main outcome variables

Total wart area; Localized Adverse reactions

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210209050303N1**
Registration date: **2022-06-10, 1401/03/20**
Registration timing: **retrospective**

Last update: **2022-06-10, 1401/03/20**
Update count: **0**

Registration date

2022-06-10, 1401/03/20

Registrant information

Name

moghadase jafari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-04-18, 1401/01/29

Expected recruitment end date
2022-05-19, 1401/02/29
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
The effect of green tea extract (sincathecin) in the treatment of patients with common and palmoplantar warts referred to the dermatology clinic of Imam Reza Hospital in Mashhad and its comparison with the control group

Public title
The effect of green tea extract in the treatment of warts
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
People 15 to 35 years old with common and palmoplantar warts who are otherwise healthy
Exclusion criteria:
Pregnant and lactating women Patient with immunodeficiency patient with underlying diseases patient with a history of skin disease or allergies to certain topical or systemic medications
Age
From **15 years** old to **35 years** old
Gender
Both

Phase
N/A
Groups that have been masked

- Outcome assessor
- Data analyser

Sample size
Target sample size: **80**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization in this study in three stages: 1- creating a random sequence, 2- hidden Random allocation is made and the randomization process is executed. 1- Creating a random sequence: Web-based randomization is used to generate a random sequence. Sequences of random numbers are generated with the help of https://kitset.ir/numbers/random. 2- Random allocation concealment: The method and tool used to perform a random sequence on the study participants is the use of opaque envelopes sealed with a random sequence. Each random sequence created is recorded on a card and the cards are placed in the envelopes of the order, respectively. Patients who meet the inclusion criteria are randomly assigned to one of the two groups. In this way, at the time of registration of the participants, based on the order of their entry into the study, one of the envelopes of the letter is opened in order and the assigned group of that participant is revealed. 3- Execution of random allocation process A: Identify the person who creates the random sequence. B: Designate a person who evaluates and registers patients in terms of inclusion and exclusion criteria. C: Determine the person who assigned the participants to the groups. The person creating the random sequence is not involved in other stages of randomization, including registration and assignment of participants, and the person involved in creating the random program is separate from other researchers.
Blinding (investigator's opinion)
Single blinded
Blinding description
The physician responsible for evaluating the results in the patients and the person in charge of the study analysis are unaware of the patients' assignment to the type of treatment. Blinding patients is not possible due to the type of intervention.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Working Group / Ethics Committee in Research, School of Medicine, Mashhad University of Medical Scie
Street address
Imam reza hospital, Mashad, Iran
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Province
Razavi Khorasan
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Approval date
2022-04-12, 1401/01/23
Ethics committee reference number
IR.MUMS.MEDICAL.REC.1401.035

Health conditions studied

1

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

Primary outcomes

1

Description
Total wart area
Timepoint
Measurement of wart lesion area at the beginning of the study (before the intervention) and the first month, second month, third month and fourth month after starting to use green tea extract. Also three months and 6 months after the end of treatment.
Method of measurement
Ruler

Secondary outcomes

1

Description
Localized Adverse reactions
Timepoint
Once every two weeks
Method of measurement
Telephone history, observation of complications

Intervention groups

1

Description
The intervention group is treated topically with green tea extract three times a day with an interval of 8 hours for 16 weeks. The green tea extract used in this study is prepared by a pharmacologist from green tea leaves and contains 15% syncatin.
Category
Treatment - Drugs

2

Description
The control group is treated with cryotherapy using liquid nitrogen once every two weeks until complete healing of the lesions.
Category
Treatment - Devices

Recruitment centers

1

Recruitment center
Name of recruitment center
Imamreza Hospiral
Full name of responsible person
Moghadase Jafari
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Sponsors / Funding sources

1

Sponsor
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Mashhad University of Medical Sciences
Full name of responsible person
Dr. Majid Ghayyur Mobarahan
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Vice Chancellor for Research and Technology, , third floor, University of Medical Sciences, next to Hoveyzeh Cinema, Mashhad, University Street, Khorasan Razavi, Iran
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Web page address
https://v-research.mums.ac.ir/
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Mashhad 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
Mashhad University of Medical Sciences

Full name of responsible person
Moghadase Jafari
Position
Dermatology Resident
Latest degree
Medical doctor
Other areas of specialty/work
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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 more information
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
No - There is not a plan to make this available
Clinical Study Report
Yes - There is 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
Title and more details about the data/document
The study protocol, statistical analysis map and clinical study report will be fully shared.
When the data will become available and for how long
Start the access period immediately after printing the results
To whom data/document is available
Everyone is interested
Under which criteria data/document could be used
There are no conditions
From where data/document is obtainable
Dr. Moghadase Jafari jafarimg971@mums.ac.ir
What processes are involved for a request to access data/document
Requests will be reviewed by researchers and will be answered within 2 working weeks.
Comments