

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### The effect of green tea extract (sincatechin) 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

+98 51 3270 2343

##### Email address

jafarimg971@mums.ac.ir

##### 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, Mashhad, Iran

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9137913316

**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 Hospital

##### Full name of responsible person

Moghadase Jafari

##### Street address

Dermatology Clinic, Imamreza Hospital, Daneshgah Street, Mashhad, Iran

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9137913316

##### Phone

+98 51 3802 2031

##### Email

jafarimg971@mums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Mashhad University of Medical Sciences

##### Full name of responsible person

Dr. Majid Ghayyur Mobarahan

##### Street address

Vice Chancellor for Research and Technology, , third floor, University of Medical Sciences, next to Hoveyzeh Cinema, Mashhad, University Street, Khorasan Razavi, Iran

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9138813944

##### Phone

+98 51 3841 1538

##### Fax

+98 51 3843 0249

##### Email

vcresraech@mums.ac.ir

##### 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**

Dermatology

**Street address**

Dermatology Clinic, Imamreza Hospital, Daneshgah Street, Mashhad, Iran

**City**

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**Person responsible for scientific 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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**Email**

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**Person responsible for updating data****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person****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**