Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 2026

Investigating the effect of ointment containing Green Tea extract and Peganum harmala in the treatment of Genital Warts in Women: a controlled randomized clinical trial

Protocol summary

Study aim

Assessing and comparing the effectiveness of gels containing green tea extract, a mixture of green tea extract and Peganum harmala seed extract (in a 50-50 ratio), and a mixture of green tea extract and Peganum harmala seed extract (in an 80-20 ratio) in the treatment of genital warts in women.

Design

A phase 2 randomized, double-blind, 3-arm, parallel-group clinical trial in 60 patients with genital warts. Randomization with https://www.sealedenvelope.com

Settings and conduct

Patients referred to Ghaem hospital, Mashhad by the researcher will be selected if they meet the inclusion and exclusion criteria will enter the random allocation process. In each group, the desired gel is applied three times a day by the patient at home on the lesion at a rate of 2 mm, and the patients are followed up by the researcher by phone once a week to ensure drug use. All three groups of patients are referred for follow-up every two weeks, and the gel box is weighed with a digital scale to ensure drug use by the patient. Then, the lesions are measured by the researcher, and the presence of unwanted inflammatory reactions such as burning, itching, redness, pain, and erosion, severity during the period, is recorded.

Participants/Inclusion and exclusion criteria

Women aged 18 to 50 years with external genital warts who do not have allergies to green tea or Peganum harmala seed extract and are not infected with any other sexually transmitted diseases.

Intervention groups

Three treatment groups: 1- gel containing green tea extract as the standard treatment,2- gel containing green tea extract and Peganum harmala seed extract in a 50-50 ratio, 3-gel containing green tea extract and Peganum harmala seed extract in an 80-20 ratio.

Main outcome variables

Number, size and location, time of onset of lesions, presence of clinical symptoms associated with lesions Visit every two weeks

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20241225064163N2**
Registration date: **2025-05-17, 1404/02/27**
Registration timing: **prospective**

Last update: **2025-05-17, 1404/02/27**
Update count: **0**

Registration date

2025-05-17, 1404/02/27

Registrant information

Name

Elham Dolat

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 51 3802 2608

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2025-05-20, 1404/02/30

Expected recruitment end date

2025-08-21, 1404/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of ointment containing Green Tea extract and Peganum harmala in the treatment of Genital Warts in Women: a controlled randomized clinical trial

Public title

The effect of ointment containing Green Tea extract and Peganum harmala in the treatment of Genital Warts in Women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The individual must not have any specific medical illnesses. They should have no other sexually transmitted diseases (STDs) In the past 6 months, they should not have been under psychiatric supervision and should not be taking psychiatric medications. They must not be allergic to green tea or pennyroyal seeds They should not have speech or behavioral disorders that hinder communication with the researcher. They must not have genital warts inside the vagina Genital warts should be limited to the skin. The number of lesions should be between 2 and 30 The surface area of lesions should be between 2 and 600 square millimeters Their spouse should not have genital warts They should have no history of using specific medications. Both they and their spouse should have only one sexual partner.

Exclusion criteria:

They are breastfeeding or pregnant. They are smoker They are infected with other STDs

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

1-2

Groups that have been masked

- Participant
- Investigator
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the Block Randomization method (with blocks of 4) will be used. For this purpose, the website https://www.sealedenvelope.com/ will be utilized.

Blinding (investigator's opinion)

Double blinded

Blinding description

For blinding purposes, the gels will be made to look similar in color and appearance to the tubes and provided to the researcher. Each tube has three different codes, which are known only to the pharmacist.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

Street address

Ahmad Abad Street

City

Mashhad

Province

Razavi Khorasan

Postal code

9919991766

Approval date

2025-04-21, 1404/02/01

Ethics committee reference number

IR.MUMS.IRH.REC.1404.022

Health conditions studied

1

Description of health condition studied

Genital warts

ICD-10 code

A63.0

ICD-10 code description

Anogenital (venereal) warts

Primary outcomes

1

Description

Number and size of external genital wart lesions

Timepoint

Every two weeks until the 10th week

Method of measurement

The patient is examined by the researcher and all areas of the genital area such as the posterior foreskin, labia majora, groin, pubic and anal areas, and perianal are examined for the presence of lesions and the number and size of the lesions are recorded. To determine the initial size of the lesion, the two main perpendicular diameters of each lesion are measured in millimeters with a ruler and the area of each lesion is obtained from the product of these two diameters.

Secondary outcomes

1

Description
Occurrence of new lesions
Timepoint
Every two weeks
Method of measurement
Observation

2

Description
Occurrence of reactions and side effects
Timepoint
Every two weeks
Method of measurement
Questioning the patient

Intervention groups

1

Description
Intervention group 1: gel containing green tea extract and pecan seeds in a 50-50 ratio
Category
Treatment - Drugs

2

Description
Control group: gel containing green tea extract
Category
Treatment - Drugs

3

Description
Intervention group 2: gel containing green tea extract and pecan seeds in a 80-20 ratio
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Ghaem Hospital
Full name of responsible person
Maliheh Hasanzade Mofrad
Street address
Department of Gynecology, Ghaem Hospital, Ahmad Abad Street, Mashhad
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Mashhad University of Medical Sciences
Full name of responsible person
Mohsen Tafaghodi
Street address
Vice Chancellor for Research and Technology, Qureshi Building, Daneshgah Street, Mashhad
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Grant name
Malihe Hasanzade Mofrad
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
Gonabad University of Medical Sciences
Full name of responsible person
Davoud Salarbashi
Position
Assistant Professor
Latest degree
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Other areas of specialty/work
Food safety and Health
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Undecided - It is not yet known if there will be a plan to make this available

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