

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jun 2026

Comparing the effects of Shallomin(a pure fraction of shallot extract) and Podophyllin solution 25% in treatment of genital HPV warts in women

Protocol summary

Summary

Objectives: Estimating and comparing the effects of Shallomin and Podophyllin solution 25% in treatment of genital HPV warts in women Design:International Setting and conduct: 60 women with major inclusion and exclusion criteria that include: being older than 15 years with genital human papilloma virus warts on the vulva with lesions less than 2 cm where be enrolled in this study. After getting a written consent, patient randomly divides into two groups. At baseline, information about the patient, and physical exam findings, such as the place and the number of the lesion will be collected Intervention: in the first group, Shalomin will be used for treatment, using an applicator to apply it on the lesion. In the second group, Podophyllin solution 25% is applied with an applicator on the lesion.Before using the drug the surrounding of the lesion is coated with zinc oxide cream. Patients were advised to wash the place after 4 hours.Patients are treated on a weekly basis until full recovery from lesion for 6 weeks and at every appointment, the number of lesions and possible side effects are recorded main outcome measures (variables): The primary outcome is the improvement of genital warts including full removal of lesion and partial recovery of lesion, which is more than 75%, respectively.If the recovery is less than 75% during the treatment period of 6 weeks, no improvement or treatment failure will be considered.The secondary outcome is side effects leading to complications including pain, irritation, and ulcer.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017011531949N1**

Registration date: **2017-03-05, 1395/12/15**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-03-05, 1395/12/15

Registrant information

Name

Shadab Shahali

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 916 614 1895

Email address

shadab.shahali@modares.ac.ir

Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapur University of Medical Sciences

Expected recruitment start date

2017-01-20, 1395/11/01

Expected recruitment end date

2018-03-06, 1396/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effects of Shallomin(a pure fraction of shallot extract) and Podophyllin solution 25% in treatment of genital HPV warts in women

Public title

Comparing the effects of Shallomin and Podophyllin solution 25% in treatment of genital HPV warts in women

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: genital HPV warts under 2cm exclusion criteria: age under 15; breast feeding; pregnancy

Age

From **15 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Single blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Ahvaz Jundishapur University of Medical Sciences

Street address

Ahvaz Jundishapur University of Medical Sciences

City

Ahvaz

Postal code

Approval date

2016-10-29, 1395/08/08

Ethics committee reference number

IR.AJUMS.REC.1395.662

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

Treatment of genital warts

Timepoint

6 week later

Method of measurement

Visit with dermatologist

Secondary outcomes

empty

Intervention groups

1

Description

In the first group, shalomin will be used for treatment, using an applicator to apply it on the lesion. Preparation of medicines: To develop pure fractions of shallot, tuber roots of the plant in the spring of Sardasht Heights is located at 50 kilometers north of Dezful will be collected. The plant's underground tubers will wash well and then crushed in a mortar Electric will be well. 100 g of crushed plants mixed with 200 ml of distilled water for 30 minutes will be severely shaken. Isolated extract from yellow to help filter paper pulp will be removed. This is repeated three times until all the juice from the pulp will be removed. Extracts obtained in a large human gathering in the oven at 45 ° C and condensed and column chromatography on silica gel stationary phase is passed. as a medicine for the treatment of genital warts caused by the human papillomavirus used to rest. It called Shallomin at the patent office called the doctor Mansour Amin as antimicrobial have been registered.

Category

Treatment - Drugs

2

Description

In the second group podophyllin solution, 25% is applied with an applicator on the lesion. Before using the drug the surrounding of the lesion is coated with zinc oxide cream. Patients were advised to wash the place after 4 hours.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Ahvaz Imam khomeini hospital

Full name of responsible person

Street address

Imam Khomeini hospital, Azadegan road, Ahvaz,

Khuzestan
City
Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Ahvaz Jundishapur
University of Medical Sciences

Full name of responsible person
Dr Makhmal zade

Street address
Ahvaz Jundishapur University of Medical Sciences

City
Ahvaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Ahvaz Jundishapur
University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person
Dr. Shadab Shahali

Position
Assistant Professor

Other areas of specialty/work

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Person responsible for scientific inquiries

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Full name of responsible person
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Position
PhD

Other areas of specialty/work

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Web page address

Person responsible for updating data

Contact

Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty