

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of the effect of cryotherapy and Podophyllin solution 25% for treatment of genital warts in women

Protocol summary

Summary

the aim of this study that is randomized clinical trial, is to determine and compare the effectiveness and adverse effects of the most common treatments of the genital warts, podophyllin solution 25% and cryotherapy. external genital warts cases who referred to the Khatam Alambia polyclinic in Yazd, are enrolled and randomly divided into two groups after considering inclusion and exclusion criteria. In the first group, liquid nitrogen is used for cryotherapy, using an applicator to apply it on the lesion. duration of cryotherapy is until the entire lesion and a millimeter of this become white, each method is applied once for any lesion. In the second group podophyllin solution 25% is applied with an applicator on 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. at baseline, information about the patient such as age, duration of disease, peaceful or disturbed matrimonial relation, and physical exam findings, such as the place and the number of lesion will be collected. 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. 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. secondary outcome is side effects leading to complications including pain, irritation and ulcer.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015090514386N1**

Registration date: **2015-09-05, 1394/06/14**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-09-05, 1394/06/14

Registrant information

Name

Maryam Sadat Torabipour

Name of organization / entity

Shahid Sadooghi University of Medical Sciences, Yazd

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Shahid Sadooghi University of Medical Sciences

Expected recruitment start date

2013-02-19, 1391/12/01

Expected recruitment end date

2015-08-22, 1394/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of cryotherapy and Podophyllin solution 25% for treatment of genital warts in women

Public title

Comparison of the effectiveness of two common treatments for genital warts

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: the existence of external genital warts in the genital area; the existence of external genital warts in the anus; female patients. Exclusion criteria: age under 15 years; pregnancy; lactation

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)

Not blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shahid Sadooghi University of Medical Sciences,Yazd

Street address

Central Office of Shahid Sadooghi University of Medical Sciences, Shahid Sadooghi blvd,Yazd

City

Yazd

Postal code

Approval date

2014-05-22, 1393/03/01

Ethics committee reference number

ir.ssu.medicine.rec.1393.3

Health conditions studied

1

Description of health condition studied

genital wart

ICD-10 code

A63.0

ICD-10 code description

Anogenital (venereal) warts

Primary outcomes

1

Description

Improvement of genital warts

Timepoint

The beginning of the study, the first week,the second week, the third week,the fourth week, the fifth week, the sixth week.

Method of measurement

Observation, physical examination

Secondary outcomes

1

Description

Side effect (burn)

Timepoint

The beginning of the study, the first week,the second week,the third week,the fourth week,the fifth week,the sixth week.

Method of measurement

Observation, physical examination

2

Description

Side effect (Swelling)

Timepoint

The beginning of the study, the first week,the second week,the third week,the fourth week,the fifth week,the sixth week.

Method of measurement

Observation, physical examination

3

Description

Side effect (pain)

Timepoint

The beginning of the study, the first week,the second week,the third week,the fourth week,the fifth week,the sixth week.

Method of measurement

Observation, physical examination

Intervention groups

1

Description

In the first group liquid nitrogen is applied on the lesion for cryotherapy and By using applicator is applied on waste. duration of cryotherapy is until the Whitening of the entire lesion and one millimeter from its border which is applied once for any lesion.

Category

Treatment - Surgery

2

Description

In the second group Podophyllin solution 25% is applied on lesion using an applicator. Before using the drug, the surrounding of the lesion around the lesion is coated with Zinc Oxide Cream. Patients are advised to completely wash place after 4 hours.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Khatamolanbia Specialty and Subspecialty Poly Clinic

Full name of responsible person

Maryam Sadat Torabipour

Street address

Taleghani blvd, Yazd

City

Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Sadooghi University of Medical Sciences, Yazd

Full name of responsible person

Amir Hushang Mehrparvar, MD

Street address

Central office of Shahid Sadooghi University of Medical Sciences, Shahid Sadooghi blvd, Yazd

City

Yazd

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Sadooghi University of Medical Sciences, Yazd

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

Shahid Sadooghi University of Medical Sciences, Yazd

Full name of responsible person

Maryam Sadat Torabipour

Position

student

Other areas of specialty/work

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Person responsible for scientific inquiries

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Assistant professor of dermatology

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Person responsible for updating data

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Position

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Other areas of specialty/work

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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