Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

Comparative effect treatment of Ficus Carica Latex cream vs. Podophyllin in treatment of Genital Warts

Protocol summary

Summary

Purpose: To determine and compare the therapeutic effect of Ficus Carica cream, and Podophyllin in the treatment of genital warts. Study a double- blind randomized clinical trial .Target Population is patients with genital warts. Inclusion Criteria: Patients with genital warts disease who have been approved by the gynecologist and oncologist, Total area of warts is not greater than 10 cm ², wart area is external genital warts and anal, Gender women, patients none of the treatments had to be received in 3 ago, Less than a year having passed from patient to patient. There is no active genital herpes lesions. No skin erythema and inflammation Exclusion Criteria: Occurrence of any serious skin condition that usually does not respond to allergy medications, HIV infection The sample size in each treatment group, 46 patients, and the overall sample size is 92. Random allocation of treatment to patients using Random Allocation Software. First step is to prepare the cream of Ficus Carica latex. Drugs used in group 2, Podophyllin 20% cream. Fig creams Group, cream 3- 4 times daily by patients to the appropriate size is placed on the stand. In the group Podophyllins 20% , cream placed by programs experts and by swab on warts will be once a week. Duration of treatment every 2 group at least 2 weeks and a maximum 8 weeks. Out comes of the study determine the effectiveness, efficacy, side effect and recurrence rates warts after 3 months of treatment compare with Podophyllin. Further determine the attributable risk (AR) and the odds ratio and number needed to treat (NNT) will be calculated in the study Population

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013111015364N1**

Registration date: **2014-06-25, 1393/04/04**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2014-06-25, 1393/04/04

Registrant information

Name

Sepideh Mahdavi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 23 3228 0917

Email address

sepideh.mahdavi@shmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Shahid Sadoghi Yazd University of Medical Sciences

Expected recruitment start date

2014-05-22, 1393/03/01

Expected recruitment end date

2015-05-22, 1394/03/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative effect treatment of Ficus Carica Latex cream vs. Podophyllin in treatment of Genital Warts

Public title

Comparative effect treatment of Ficus Carica Latex

cream vs. Podophyllin in treatment of Genital Warts

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Patients with genital warts disease who have been approved by the gynecologist and oncologist. Total area of warts is not greater than 10 cm ², wart area is external genital warts and anal, Gender women, patients none of the treatments had to be received in 3 month ago, Less than a year having passed from patient to patient. There is no active genital herpes lesions. No skin erythema and inflammation Exclusion Criteria: Occurrence of any serious skin condition that usually does not respond to allergy medications, HIV infection

Age

No age limit

Gender

Female

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **92**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double 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 Shahid Sadoghi University of Medical Science

Street address

Health College, Shahid Sadoghi University of Medical Science, Daneshjo Bolvar, Emam Hosein Square, Yazd

City

Yazd

Postal code

91165-887

Approval date

2013-07-29, 1392/05/07

Ethics committee reference number

17/1/81438/پ

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

Comparative effect treatment of Ficus Carica Latex cream and Podophyllin in treatment of Genital Warts

Timepoint

Before intervention, One month after the intervention, 8 week after the intervention, one months after the end of intervention

Method of measurement

Number and total area of warts and warts in the beginning and during the treatment, Visit and use Photography

Secondary outcomes

1

Description

Determine and Compare side effect of Ficus Carica Latex cream vs. Podophyllin in treatment of Genital Warts

Timepoint

One month after the intervention- After the intervention

Method of measurement

A visual examination by a gynecologist- A patient questionnaire complications include itching, burning, pain, and inflammation

2

Description

Determine and compare the recurrence rate of genital warts after one months after completion of treatment in both treatment groups

Timepoint

One months after the intervention.

Method of measurement

Photo taken from the baseline and end of treatment. Counting the number of warts- Warts area Comparison

3

Description

Determine and compare patient satisfaction with treatment compared with Ficus Carica cream vs Podophyllin

Timepoint

After treatment

Method of measurement

Questionnaire including questions of overall satisfaction, satisfaction with treatment site, and overall satisfaction with the group treated with 5 benchmark score

Intervention groups

1

Description
The intervention in case group is by Ficus Carica latex cream. This cream pharmaceutical processes using latex of Figs and pharmaceutical base creams and Vaseline with varying proportions of each material is produced. Cream is made of 20% Fig latex. Term use of this cream will be at least 2 weeks and a maximum of 8 weeks. Cream 3- 4 times daily by the patients themselves and by the swab is placed on warts

Category
Treatment - Drugs

2

Description
Control group using standard methods of genital warts treatment is called Podophyllin. Podophyllin 20% in this study is used in the cream forms. Treatment in this group will be at least two weeks and a maximum of 8 weeks. Cream once a week by an programs expert is placed on the warts and be patient to wait for a few minutes on the bed and get up out of bed and put on clothes.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Baghai por clinic,Shahid Sadoghi hospital in Yazd

Full name of responsible person
Doctor Mozhgan Karimi

Street address
Ebne Sina street ,Sh.Ghandi bolvar, Safaie, Yazd

City
Yazd

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice chancellor for research, Shahid Sadoghi Yazd University of Medical Sciences

Full name of responsible person
Dr. Fateme Ezeddini

Street address
Vice chancellor for research, Headquarters of Shahid Sadoghi University of Medical Science, Bahonar Square, yazd

City
Yazd

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, Shahid Sadoghi Yazd 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
Health College, Shahid Sadoghi University of Medical Science

Full name of responsible person
Sepideh Mahdavi

Position
Post graduate student/ Epidemiology

Other areas of specialty/work

Street address
4 Floor, 114 Number, Elahi street(216East street), Fourth Sguare Tehran Pars, Tehran

City
Tehran

Postal code

Phone
+98 21 7706 1380

Fax

Email
sepideh.mahdavi@ssu.ac.ir; s.mahdavi88@gmail.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Health College, Shahid Sadoghi University of Medical Science

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Sepideh Mahdavi

Position
Post graduate student/ Epidemiology

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Street address
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Postal code

Phone

+98 21 7706 1380

Fax

Email

sepideh.mahdavi@ssu.ac.ir; s.mahdavi88@gmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

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Street address

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Postal code

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+98 21 7706 1380

Fax

Email

sepideh.mahdavi@ssu.ac.ir

Web page address

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