Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Evaluation of efficacy of 5% formalin in treatment of female genital warts comparing to cryotherapy

Protocol summary

Study aim

Our purpose in this study is to evaluate the therapeutic effect of formalin 5% solution as an affordable and low-cost treatment on female genital warts.

Design

80 patients with at least 2 similar genital warts are included in the clinical trial with parallel groups in terms of appearance and size. A lesion is treated with 5% formalin solution and the same lesion is treated with cryotherapy. Other lesions are also treated with cryotherapy.

Settings and conduct

The largest diameter of one of the lesions of women with genital warts referring to Dermatology Clinic of Shahid Faghihi Hospital of Shiraz is recorded. 5% formalin solution is applied to the lesion for 10 minutes. This is repeated every day by the patient. The size of the largest diameter of the same lesion is also recorded.The lesion is treated by a physician weekly with cryotherapy. Patients are visited weekly for 4 weeks. The size of the lesions and possible side effects of both treatments are recorded Carefully.

Participants/Inclusion and exclusion criteria

All women with genital warts referring to the dermatology clinic for cryotherapy with at least two or more genital warts of similar appearance and size, in the absence of pregnancy and lactation, immune deficiency, coagulation disorders, other sexually transmitted diseases, or other active skin diseases at the treatment site are included in the study, if they are satisfied.

Intervention groups

One of the lesions is considered as a selective lesion treated with formalin and a lesion of the same size as a selective lesion treated with cryotherapy and as a control group. The size of both lesions and possible side effects are carefully recorded.

Main outcome variables

The rate of reduction in the size of the lesions and the overall recovery are compared in both treatments.

Complications of both treatments are recorded.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190714044200N1**
Registration date: **2020-05-04, 1399/02/15**
Registration timing: **registered_while_recruiting**

Last update: **2020-05-04, 1399/02/15**
Update count: **0**

Registration date

2020-05-04, 1399/02/15

Registrant information

Name

Amir Miri

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3231 9049

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-02-20, 1398/12/01

Expected recruitment end date

2020-08-22, 1399/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of efficacy of 5% formalin in treatment of female genital warts comparing to cryotherapy

Public title
The effect of formalin on treatment of genital warts

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
All female patients with external genital warts referred for treatment with cryotherapy Patients should have at least 2 genital warts of the same size and appearance.

Exclusion criteria:
A wound or active skin disease other than wart at the treatment site Coagulation disorder The presence of other sexually transmitted diseases Immunodeficiency, such as HIV infection Using topical anti viral medications in the last two weeks Pregnancy and lactation Lesions in the internal genital system, such as vagina and cervix

Age
No age limit

Gender
Female

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **80**
More than 1 sample in each individual
Number of samples in each individual: **2**
Each lesion is independently considered as a sample. One of the lesions is considered as a selective lesion for treating with formalin and a lesion of the same size as a selective lesion undergoing cryotherapy

Randomization (investigator's opinion)
Not randomized

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features
Patients with genital warts who have two or more lesions are included in the study, and each lesion is independently considered as a sample. One of the lesions is considered as a selective lesion for treating with formalin and a lesion of the same size as a selective lesion undergoing cryotherapy.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics Committee of Shiraz University of Medical Sciences

Street address
Headquarters Of Shiraz University of Medical Sciences - Zand St - Shiraz

City
Shiraz

Province
Fars

Postal code
34786-71946

Approval date
2016-06-08, 1395/03/19

Ethics committee reference number
IR.SUMS.REC.1395.S171

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
measurement of genital wart size in female patients

Timepoint
At the beginning of the study, one week later, two weeks later, three weeks later, four weeks after starting treatment

Method of measurement
caliper

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The patient uses the 5% formalin solution in the collodion base provided by the hospital pharmacist on the genital warts topically by an applicator daily for 10 minutes.

Category
Treatment - Drugs

2

Description
Control group: Cryotherapy of genital warts is done weekly by a dermatologist. The device manufactured by the company Iran Sarma darman is used and The chemical substance used in this method is a liquid nitrogen with temperature of -198. Each cryotherapy session is performed for two 20-second freezing cycles and a 60 second thawing cycle.

Category
Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Dermatology Clinic, Shahid Faghih Hospital of Shiraz University of Medical Sciences

Full name of responsible person
Amir Miri

Street address
Zand Blvd, Shahid Faghihi Hospital, Dermatology Department office

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Dr Younes Ghasemi

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Grant name

Grant code / Reference number

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

Title of funding source
Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
Mahsa Razeghi

Position
Resident of obstetrics and gynecology

Latest degree
Medical doctor

Other areas of specialty/work
Gynecology and Obstetrics

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Person responsible for scientific inquiries

Contact

Name of organization / entity
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Full name of responsible person
Bahia Namavar Jahromi

Position
professor of Obstetrics and Gynecology

Latest degree
Subspecialist

Other areas of specialty/work
Gynecology and Obstetrics

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Person responsible for updating data

Contact
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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)
Yes - There is 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
Undecided - It is not yet known if there will be a plan to make this available
Informed Consent Form
Undecided - It is not yet known if there will be a plan to make this available
Clinical Study Report
Undecided - It is not yet known if there will be a plan to make this available
Analytic Code
Undecided - It is not yet known if there will be a plan to make this available
Data Dictionary
Undecided - It is not yet known if there will be a plan to make this available
Title and more details about the data/document
Information and data from the research: Information on the main outcome
When the data will become available and for how long
Start the access period 6 months after printing the results
To whom data/document is available
Researchers working in academic institutions
Under which criteria data/document could be used
Information on the main outcome in the form of correspondence with researchers
From where data/document is obtainable
OB & Gyn ward Shiraz university of medical sciences
What processes are involved for a request to access data/document
After applying to the office of the Department of OB And GYN of Shiraz University of Medical Sciences, this request is sent to the university's vice chancellor. If the information is agreed upon, it is provided to the applicant. The approximate duration of this process is one week.
Comments