

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 May 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

miria@sums.ac.ir

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

City

Shiraz

Province

Fars

Postal code

7134846114

Phone

+98 71 3231 9049

Fax

+98 71 3233 1634

Email

miria@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Younes Ghasemi

Street address

Headquarters Of Shiraz University of Medical Sciences - Zand Blvd

City

Shiraz

Province

Fars

Postal code

3478671946

Phone

+98 71 3235 7282

Email

ghasemiy@sums.ac.ir

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

Street address

Department of obstetrics and gynecology, Shahid Faghihi Hospital, Zand St, Shiraz, Iran

City

Shiraz

Province

Fars

Postal code

7134846114

Phone

+98 71 3225 2618

Email

r_mahsa_2000@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

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

Street address

Department of obstetrics and gynecology, Shahid Faghihi Hospital, Zand St, Shiraz, Iran

City
Shiraz
Province
Fars
Postal code
7134846114
Phone
+98 71 3233 2365
Email
namavarb@sums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences
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
Street address
Department of obstetrics and gynecology, Shahid
Faghihi Hospital, Zand St, Shiraz, Iran
City
Shiraz
Province
Fars
Postal code
7134846114
Phone
+98 71 3233 2365
Email
namavarb@sums.ac.ir

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