

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jun 2026

Comparative study on the efficacy of cryotherapy and intralesional injection of Bleomycin in treatment of anogenital wart

Protocol summary

Registration timing: **registered_while_recruiting**

Study aim

Comparative study on the efficacy of two methods of cryotherapy with intralesional injection of bleomycin in treatment of anogenital wart in patients referred to Shohada-e-Tajrish and Loghman Hakim Hospitals in Tehran in 2019-2020

Last update: **2019-12-30, 1398/10/09**

Update count: **0**

Registration date

2019-12-30, 1398/10/09

Design

Patients are divided into two groups of 30. Also, to randomize the treatment, patients receive two envelopes, one containing "cryotherapy" phrase and one containing "bleomycin" phrase on a piece of paper, and the patient randomly selects one of them.

Registrant information

Name

Nasim Gholizadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

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Settings and conduct

This study is carried out at dermatology clinics of Shohada Tajrish Hospital and Loghman Hakim Hospital, which based on the selected treatment modality the cryotherapy group are treated with liquid nitrogen by cotton swab while the other group receive intra-lesional bleomycin.

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Over 18 years old; informed consent.

Exclusion criteria: Immunodeficiency; Drug allergies;

Other co-morbidities such as anogenital herpes infection;

Vascular problems; Pregnant or breast feeding; Being

under treatment in the last 4 weeks (such as cryotherapy or Imiquimod ointment); Warts on the shaft of penis.

Expected recruitment start date

2019-08-23, 1398/06/01

Expected recruitment end date

2020-12-21, 1399/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Intervention groups

Intervention group 1: Cryotherapy of anogenital wart

Intervention group 2: Intra-lesional injection of bleomycin

Trial completion date

empty

Main outcome variables

Treatment of Anogenital wart

Scientific title

Comparative study on the efficacy of cryotherapy and intralesional injection of Bleomycin in treatment of anogenital wart

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190519043631N1**

Registration date: **2019-12-30, 1398/10/09**

Public title

The efficacy of two methods of cryotherapy with intralesional injection of Bleomycin in treatment of

anogenital wart

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with anogenital wart referred to Loghman Hakim and Shohada-e-Tajrish hospitals during the years 2019-2020 Age over 18 years old Having informed consent to participate in the study

Exclusion criteria:

Immunodeficiency Drug allergy Other comorbidities such as herpes at the anogenital site Pregnancy and breast feeding Vascular disorders Receiving other treatments in the last 4 weeks (For example Cryotherapy or Imiquimod Ointment) Wart on shaft of penis

Age

From **18 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

To randomize the treatment, patients receive two envelopes, one containing "cryotherapy" phrase and one containing "bleomycin" phrase on a piece of paper, and the patient randomly selects one of them.

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

Ethics committee of Shahid Beheshti University of Medical Sciences

Street address

Shohada hospital , Tajrish Square

City

Tehran

Province

Tehran

Postal code

1989934148

Approval date

2019-04-14, 1398/01/25

Ethics committee reference number

IR.SBMU.SRC.REC.1398.002

Health conditions studied

1

Description of health condition studied

Anogenital wart

ICD-10 code

A63.0

ICD-10 code description

Anogenital (venereal) warts

Primary outcomes

1

Description

Treatment of Anogenital wart

Timepoint

At 3-week intervals for 3 times

Method of measurement

Observation by dermatology resident

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Cryotherapy ; Liquid nitrogen is applied with a cotton swab on lesions for two Freeze-Taw cycles and then intra-lesional normal saline is injected as a placebo.

Category

Treatment - Drugs

2

Description

Intervention group 2: Intralesional injection of bleomycin ; The bleomycin vial 15 mg is dissolved in 5 cc normal saline and injected at 2: 1 ratio with lidocaine into the lesions (equivalent to 2 mg /ml).

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shohada-e-Tajrish Hospital

Full name of responsible person

Nasim Gholizadeh

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Tajrish Square
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
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Grant name

Grant code / Reference number

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

No

Title of funding source

Shahid Beheshti 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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Nasim Gholizadeh
Position
Resident
Latest degree

Medical doctor
Other areas of specialty/work
Dermatology
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Person responsible for updating data

Contact

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

There is no more information.

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