

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

A parallel, self-controlled clinical trial to determine the healing effect of WARTNER in male patients with genital wart

Protocol summary

Summary

This is a phase 3 parallel, self controlled clinical trial with before-after measurement for evaluating effectiveness of local WARTNER in the treatment of genital warts. Subjects are 20 more than 18 years old men with genital wart who has been referred to TUMS skin and leprosy diseases research center. Eligible patient are sufficiently informed about objectives, potential adverse events and method of responsiveness. Patients are referred to dermal lab and are given informed consent. after registration of patients, subject identification form is assigned to each patient. 20 patients are included. 2 random lesion are selected for each patient and WARTNER is used to treat one of them. The other lesion is considered as control. both lesions are photographed. All patients are recommended to clean the site and come again after 14 days. At that time, both lesions are assessed by size and clearance (total removal of lesion). Primary outcome is two week difference in size of the intervention lesion compared to control one.

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Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Manoosha-Daru pharmaceutical Co.

Expected recruitment start date

2015-04-21, 1394/02/01

Expected recruitment end date

2015-09-23, 1394/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138811073200N1**

Registration date: **2015-04-11, 1394/01/22**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2015-04-11, 1394/01/22

Registrant information

Name

Kazem Heidari

Name of organization / entity

Scientific title

A parallel, self-controlled clinical trial to determine the healing effect of WARTNER in male patients with genital wart

Public title

Efficacy of WARTNER anti-wart local drug on genital warts

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Male sex, ≥ 18 years old of age, at least 2 genital wart lesion approved by dermatologist, consent to participate and being followed for visits, consent to discontinue the other anti-genital wart drugs
Exclusion criteria: diagnosed case of diabetes mellitus, Drug addiction, Other STDs, HIV positive, other immunodeficiency diseases, active skin lesion in genital

ares, serious adverse event or intolerance to previous cryotherapy , cold sensitivity history, any tattoo, scar or pigmentation in the field of intervention which could affect the evaluation of the site, Being in the waiting list or participation in another cryotherapy trial at the same time of our study

Age

From **18 years** old to **139 years** old

Gender

Male

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **20**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Tehran university of medical sciences, ethics committee

Street address

TUMS central building, Keshavarz Blvd.

City

Tehran

Postal code

1346694135

Approval date

2015-04-07, 1394/01/18

Ethics committee reference number

94-01-159-28140-141082

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

intervention and control lesion size

Timepoint

Days 0 and 14

Method of measurement

Caliper and Camera

Secondary outcomes

1

Description

Clearance of lesion

Timepoint

Day 14

Method of measurement

Observation and photography

2

Description

Adverse event

Timepoint

2 weeks after intervention

Method of measurement

Patient information

3

Description

lesion recurrence

Timepoint

6 weeks after intervention

Method of measurement

observation

Intervention groups

1

Description

Control lesion: no intervention

Category

N/A

2

Description

Intervention lesion: according to instruction, applicator is placed in sponge section. Then aerocel can is contacted to applicator and sponge is cryoliquid polluted. After waiting for 20 seconds, applicator is placed on the intervention lesion for 20 seconds.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Center For Research And Training In Skin Diseases
And Leprosy

Full name of responsible person

Alireza Firooz

Street address

No. 415, Taleqni Ave

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Manoosha-Daru

Full name of responsible person

Dr Mohamad Asnavandi

Street address

Unit 9, 3rd floor, No 12, 4th alley, in front of Tehran
clinic, Ghaem-magham street

City

Tehran

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Manoosha-Daru

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

Center For Research And Training In Skin Diseases
And Leprosy

Full name of responsible person

Alireza Firooz

Position

Professor

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