Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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.

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

Tehran University of Medical Sciences

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

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 cryotherpy 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 aerocele 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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Person responsible for scientific inquiries

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Person responsible for updating data

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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