

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of combination of cryotherapy & multipuncture intralesional injection of bleomycin and cryotherapy alone in treatment of resistant palmaplanter Warts

Protocol summary

Study aim

Effect of combination of cryotherapy and intralesional bleomycin injection in treatment of recalcitrant palmaplanter warts

Design

This is a randomized, double-blind, parallel-group, controlled phase III study. In this study, 60 patients with hand and foot resistant palmaplanter warts will be randomly divided into two groups of 30 in each, using RandList software. The control group will only receive cryotherapy and in the intervention group, in addition to cryotherapy, intralesional injection of bleomycin will be performed.

Settings and conduct

Sixty patients with palmaplanter warts who will refer to Sina Hospital Dermatology Clinic will randomly be assigned into two groups of 30 subjects, intervention group (cryotherapy and intralesional injection of bleomycin) and the control group (cryotherapy).

Participants/Inclusion and exclusion criteria

Inclusion criteria: 18- 50 years old patients with recalcitrant palmaplanter wart for more than 2 years. Exclusion criteria: Patients with injection phobia; Patients with Raynaud or Rheumatologic disorder history; Patients with allergy to local anesthetics.

Intervention groups

Intervention group: Cryotherapy and intralesional injection of bleomycin. In the intervention group, 30 patients with palmaplanter warts will be treated with cryotherapy in combination with intralesional injection of bleomycin (1 mg/ml) at the start of the study, and in case of failure at weeks 3 and 6 of the study. Control group: Only cryotherapy In the control group, 30 patients with palmaplanter warts will be treated with cryotherapy at the onset of the study and in case of failure, in the third and sixth weeks of the study.

Main outcome variables

Number of warts; diameter of the largest wart; rate of improvement; probable side effects; relapse rate

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20120524009844N6**

Registration date: **2019-04-08, 1398/01/19**

Registration timing: **prospective**

Last update: **2019-04-08, 1398/01/19**

Update count: **0**

Registration date

2019-04-08, 1398/01/19

Registrant information

Name

Mehdi Amirnia

Name of organization / entity

Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1540 6612

Email address

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-21, 1398/02/01

Expected recruitment end date

2019-11-22, 1398/09/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of combination of cryotherapy & multipuncture intralesional injection of bleomycin and cryotherapy alone in treatment of resistant palmaplanter Warts

Public title

Evaluation of intralesional injection and multipuncture of bleomycin in resistant palmaplanter Warts

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Patients with palmoplantar wart resistant to treatment
Have disease for more than 2 years
Patients with age range of 18- 50 years old

Exclusion criteria:

Patients with Injection phobia
Patients with Raynaud or Rheumatologic disorder history
Patients with allergy to local anesthetics

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

A simple randomization will be carried out on an individual basis by RandList software. The allocation will be sealed by an independent monitor and will not be broken until the end of the study.

Blinding (investigator's opinion)

Double blinded

Blinding description

The investigator assessing outcome and analyzing the data will be blinded to treatment allocation until the end of the study.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethics committee of Tabriz University of Medical Sciences

Street address

Sina Hospital, Azadi street, Tabriz

City

Tabriz

Province

East Azarbaijan

Postal code

5163639888

Approval date

2018-12-12, 1397/09/21

Ethics committee reference number

IR.TBZMED.REC.1397.817

Health conditions studied**1****Description of health condition studied**

resistant palmaplanter Warts

ICD-10 code

B07

ICD-10 code description

Viral warts

Primary outcomes**1****Description**

Numbers of Warts

Timepoint

weeks 0,3,6 and 9

Method of measurement

Counting

2**Description**

Diameter of the largest wart

Timepoint

Weeks 0,3,6,9

Method of measurement

Measure by ruler

Secondary outcomes**1****Description**

Improvement

Timepoint

Weeks 3, 6, 9

Method of measurement

Observation

2

Description

Probable side effects

Timepoint

Weeks 3, 6, 9

Method of measurement

Observation

3

Description

Disease relapse

Timepoint

weeks 3, 6, 9

Method of measurement

Observation

Intervention groups

1

Description

Intervention group: Cryotherapy and intralesional injection of bleomycin. In the intervention group, 30 patients with palmoplantar warts will be treated with cryotherapy in combination with intralesional injection of bleomycin (1 mg/ml) at the start of the study, and in case of failure at weeks 3 and 6 of the study.

Category

Treatment - Other

2

Description

Control group: Only cryotherapy In the control group, 30 patients with palmoplantar warts will be treated with cryotherapy at the onset of the study and in case of failure, in the third and sixth weeks of the study.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

Dr. Mehdi Amirnia

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Azadi Street

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Email

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Ataa Mahmoudpour

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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

Tabriz 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

Tabriz University of Medical Sciences

Full name of responsible person

دکتر مهدی امیرنیا

Position

professor

Latest degree

Specialist

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

All data will be shared after being unidentified.

When the data will become available and for how long

At any time

To whom data/document is available

It will be free for everyone.

Under which criteria data/document could be used

There are no special conditions

From where data/document is obtainable

Email: mehamir46@gmail.com Dr Mehdi Amirnia
09143113577 Dermatology Department - Sina Hospital-
Azadi Street- Tabriz

What processes are involved for a request to access data/document

The Request will be checked, then data will be sent by
Email in 1 month.

Comments