

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison the efficacy of combined treatment of micro needling plus topical bleomycin versus cryotherapy for the treatment of hand and foot refractory warts

Protocol summary

Study aim

Comparison the efficacy of combined treatment of micro needling plus topical bleomycin versus cryotherapy for the treatment of hand and foot refractory warts

Design

A parallel-group, triple-blind, randomized, phase 3 clinical trial on 90 patients. A sealed envelope was used for randomization.

Settings and conduct

This study will be conducted in Sina Tabriz Hospital. Blinding was performed for the clinical observer, the analyzer and the outcome assessor.

Participants/Inclusion and exclusion criteria

Patients with treatment-resistant warts and those who have consented to participate in the study will be included. Pregnant and lactating women, children under four years old, older people over 65 years old, patients under immunosuppressive treatment, patients with immunodeficiency and hypersensitivity reactions, vascular diseases, Raynaud's phenomenon, patients with capillary filling more than two seconds and patients with rheumatological disorders will be excluded from the study.

Intervention groups

Intervention group 1: Micro-needle is applied to patients once every two weeks. After initial micro-needling, a bleomycin solution of 1 unit/cc is prepared and placed on the site. Micro-needling is used again to deliver bleomycin to the underlying layers, and patients are treated four times at 2-week intervals. Intervention group 2: For cryotherapy, liquid nitrogen is applied for two cycles of freezing and thawing using a manual spray. The spray gun is kept perpendicular to the wart at a distance of 1 to 2 cm, and the wart is sprayed until the formation of an ice ball spreads from the center to the edge of the wart and a margin of 1 to 2 mm.

Main outcome variables

Treatment effectiveness from the physician's point of view, treatment effectiveness from the patient's point of view and local pain

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20221109056452N1**

Registration date: **2023-02-15, 1401/11/26**

Registration timing: **prospective**

Last update: **2023-02-15, 1401/11/26**

Update count: **0**

Registration date

2023-02-15, 1401/11/26

Registrant information

Name

Roya Vatankhah

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3277 6395

Email address

royvtn90@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-03-06, 1401/12/15

Expected recruitment end date

2023-04-20, 1402/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the efficacy of combined treatment of micro needling plus topical bleomycin versus cryotherapy for the treatment of hand and foot refractory warts

Public title

Efficacy of combined topical treatment versus cryotherapy for the treatment of refractory warts

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Treatment-resistant warts Consent to participate in the study

Exclusion criteria:

Pregnant and lactating women Children under four years old People over 65 years old Patients under immunosuppressive treatment Patients with immunodeficiency and hypersensitivity reactions Patients with vascular diseases Patients with Raynaud's phenomenon Patients with capillary filling more than two seconds Patients with rheumatological disorders

Age

To 65 years old

Gender

Both

Phase

3

Groups that have been masked

- Care provider
- Outcome assessor
- Data analyser

Sample size

Target sample size: 90

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be using sealed envelopes, of which 90 envelopes will be selected in total and will be divided into two groups of 45, including groups A and B. Envelopes will be selected by the operating room nurse who is blind to the study groups. Group A will be the intervention group 1, group B will be the intervention group 2.

Blinding (investigator's opinion)

Triple blinded

Blinding description

Blinding was done for the analyzer and outcome evaluator, and the research analyst and outcome evaluator were wholly blinded to the treatment methods performed in the researched patients.

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

Third Floor, Central Building of Number 2, Golgasht Street

City

Tabriz

Province

East Azarbaijan

Postal code

5138665793

Approval date

2023-02-06, 1401/11/17

Ethics committee reference number

IR.TBZMED.REC.1401.1004

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

Hand and foot wart

ICD-10 code

B07.0

ICD-10 code description

Plantar wart

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

Effectiveness of treatment according to the physician

Timepoint

4 and 8 weeks after intervention

Method of measurement

Physician global assessment

2**Description**

Effectiveness of treatment according to the patient

Timepoint

4 and 8 weeks after intervention

Method of measurement

Patient global assessment

3**Description**

Local pain

Timepoint

4 and 8 weeks after intervention

Method of measurement

Visual analogue scale

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group 1: Micro-needle is applied to patients once every two weeks. After initial micro-needling, a bleomycin solution of 1 unit/cc is prepared and placed on the site. Micro-needling is used again to deliver bleomycin to the underlying layers, and patients are treated four times at 2-week intervals.

Category

Treatment - Drugs

2

Description

Intervention group 2: For cryotherapy, liquid nitrogen is applied for two cycles of freezing and thawing using a hand spray. The spray gun is kept perpendicular to the wart at a distance of 1 to 2 cm, and the wart is sprayed until the formation of an ice ball spreads from the center to the edge of the wart and a margin of 1 to 2 mm.

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Dermatology Clinic of Sina Hospital

Full name of responsible person

Dr. Afsaneh Radmehr

Street address

Dermatology ward, Sina Hospital, Azadi Ave

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Tabriz

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East Azarbaijan

Postal code

5138665793

Phone

+98 41 3541 2103

Email

dr82radmehr@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Abolghasem Jouyban

Street address

Third Floor, Central Building of Number 2, Golgasht Street

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Tabriz

Province

East Azarbaijan

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51386631357

Phone

+98 41 3553 9161

Email

lahroudin@gmail.com

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

Dr. Roya Vatankhah

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

No.23, Pasdaran allay, Shahid golestani street, Homafar1 street

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royvtn90@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Tabriz University of Medical Sciences

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Dr. Roya Vatankhah

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Resident

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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

No - There is not 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

Study data is categorized and coded with no identifiable individuals.

When the data will become available and for how long

Access to study data after publication of the result is available in the journal.

To whom data/document is available

Anyone interested in using the data can access the study data.

Under which criteria data/document could be used

Study data can be used for comparison with other results.

From where data/document is obtainable

Refer to the study's scientific or public accountability person for data.

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

The request will be sent by email to person responsible for scientific or public inquiries.

Comments