Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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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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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Person responsible for scientific inquiries

Contact

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Tabriz University of Medical Sciences

Full name of responsible person
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