

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparative efficacy of intralesional Cryotherapy vs intralesional Corticosteroid 5 Fluorouracil in the treatment of hypertrophic scars and keloids

#### Protocol summary

##### Study aim

Comparative efficacy of intralesional Cryotherapy vs intralesional Corticosteroid . 5 Fluorouracil in the treatment of hypertrophic scars and keloids

##### Design

This interventional research would be conducted on patients with hypertrophic and colloid, admitted to the Skin Clinic of Sina Hospital from August 2016 to May 2017, after being approved by the Research Committee and the Ethics Committee. This research is double-blinded experimental, interventional (clinical trial) study, in which researcher and patient are not aware of the treatment method, and patients would be distinguished with manual coding. A checklist would be prepared by the research executor and it would be completed individually by each patient. Then, the patients would be randomly assigned to three distinct groups based on random numbers table, and each stage would be evaluated by the project assistant. The number of subjects in each group would be 21. The first group would be treated with intralesional injection of cryotherapy. The second and third groups would be treated with intralesional injection of steroids and 5-fluoroacrylate, respectively. Before starting treatment, the type of scar (hypertrophic or colloid) is determined and its size is measured and it would be recorded along with the appearance characteristics, such as color, erythema, telangiectasia, and symptoms associated with the lesion. Cryotherapy would be injected intralesionally using a special probe and freezing within the tissue. The steroid used in this research is triamcinolone 40 mg / ml and the amount of its intralesional injection would be 0.2 ml / cm<sup>2</sup>. The amount of intralesional injection for 5-fluorouracil 250 ml / 5 ml would be 0.2 ml/cm<sup>2</sup>. Treatment would be repeated every 4 weeks and up to 6 sessions, depending on the scar tissue. Before and after treatment, image of lesions is prepared. Scar severity is

measured using the vernier scale. In each treatment session, the size and appearance of scars are examined and recorded in the checklist.

##### Settings and conduct

This interventional research would be conducted on patients with hypertrophic and colloid, admitted to the Skin Clinic of Sina Hospital from August 2016 to May 2017, after being approved by the Research Committee and the Ethics Committee.

##### Participants/Inclusion and exclusion criteria

Patients with Hypertrophic Osteoarthritis and Osteoarthritis will be studied and The exclusion criteria of research include pregnant and breastfeeding women, age less than 12 years, history of allergy to the drugs used in the research, patients with uncontrolled blood pressure, liver and kidney disease, immune system deficiency and reduction in blood cell levels.

##### Intervention groups

The first group would be treated with intralesional injection of cryotherapy. The second and third groups would be treated with intralesional injection of steroids and 5-fluoroacrylate, respectively

##### Main outcome variables

Scar Volume

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20100314003566N9**

Registration date: **2018-03-04, 1396/12/13**

Registration timing: **registered\_while\_recruiting**

Last update: **2018-03-04, 1396/12/13**

Update count: **0**

##### Registration date

2018-03-04, 1396/12/13

## Registrant information

### Name

Hamide Azimi

### Name of organization / entity

Tabriz University of Medical Sciences

### Country

Iran (Islamic Republic of)

### Phone

+98 41 1540 6612

### Email address

azimih@tbzmed.ac.ir

## Recruitment status

**Recruitment complete**

## Funding source

## Expected recruitment start date

2018-01-30, 1396/11/10

## Expected recruitment end date

2019-05-31, 1398/03/10

## Actual recruitment start date

empty

## Actual recruitment end date

empty

## Trial completion date

empty

## Scientific title

Comparative efficacy of intralesional Cryotherapy vs intralesional Corticosteroid 5 Fluorouracil in the treatment of hypertrophic scars and keloids

## Public title

Comparative efficacy of intralesional Cryotherapy vs intralesional Corticosteroid 5 Fluorouracil in the treatment of hypertrophic scars and keloids

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

Patients withof hypertrophic scars and keloids Age 12 and older

### Exclusion criteria:

Pregnant Breastfeeding women Age less than 12 years history of allergy to the drugs used in the research liver and kidney disease Immune system deficiency Reduction in blood cell levels

## Age

From **12 years** old

## Gender

Both

## Phase

2-3

## Groups that have been masked

- Participant
- Investigator

## Sample size

Target sample size: **63**

## Randomization (investigator's opinion)

Randomized

## Randomization description

This research is double-blinded experimental, interventional (clinical trial) study, in which researcher and patient are not aware of the treatment method, and patients would be distinguished with manual coding. The patients are then randomly assigned to three distinct groups randomly by a random number table.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

This research is double-blinded experimental, interventional (clinical trial) study, in which researcher and patient are not aware of the treatment method, and patients would be distinguished with manual coding. The checklist will be prepared by the executor and will be completed individually for each patient, and then the patients will be randomly assigned to three distinct groups randomly by random number table, and each step will be evaluated by assistant. Each method is performed by needle insertion after anesthesia which patient will be not aware of the material. The research is performed by executor and treatment response is analyzed by assistant.

## Placebo

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 Number2, Golgasht Street

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5138665793

#### Approval date

2017-06-08, 1396/03/18

#### Ethics committee reference number

IR.TBZMED.REC.1396.193

## Health conditions studied

### 1

#### Description of health condition studied

Other disorders of skin and subcutaneous tissue in diseases classified elsewhere

#### ICD-10 code

L99

### ICD-10 code description

Other disorders of skin and subcutaneous tissue in diseases classified elsewhere

## Primary outcomes

### 1

#### Description

Scar Volume

#### Timepoint

Every 4 weeks, depending on the scar tissue, up to 6 sessions

#### Method of measurement

Using the vernier scale tool

## Secondary outcomes

### 1

#### Description

Complications of treatment

#### Timepoint

Monthly, up to 6 months

#### Method of measurement

Clinical observation

## Intervention groups

### 1

#### Description

Intervention group: The first group will be treated with Intra lesional cryotherapy(sarmadarman co./iran) alone.In this method, a liquid nitrogen at a temperature of -196 c through a probe leads to freezing of the lesion.Treatment every 4 weeks, depending on the scar tissue, will be repeated up to 6 sessions.

#### Category

Treatment - Other

### 2

#### Description

Intervention group 2: Triamcinolone 40 mg / ml will be injected by 27 gauge needle into the lesion in the amount of 0.2 ml / cm<sup>2</sup> (steroid used in this study is triamhexal.)Treatment every 4 weeks, depending on the scar tissue, will be repeated up to 6 sessions.

#### Category

Treatment - Drugs

### 3

#### Description

Intervention group3: 5Fluorouracil(EBEWE.CO) 250 mg / 5mg (0.2 ml / cm<sup>2</sup>) will be injected into the lesion by 27gauge needle.Treatment every 4 weeks, depending on the scar tissue, will be repeated up to 6 sessions.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Dermatology Clinic of Sina Hospital

##### Full name of responsible person

Dr.Hamideh Azimi

##### Street address

Dermatology ward, Sina Hospital, Azadi Ave.

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

5138665793

##### Phone

+98 41 3541 2103

##### Email

azimi@tbzmed.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Vice chancellor for Research,Tabriz University Of Medical Sciences

##### Full name of responsible person

Dr.Abolghasem Juiban

##### Street address

Third Floor, Central Building of Number2, Golgasht Street

##### City

Tabriz

##### Province

East Azarbaijan

##### Postal code

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

Vice chancellor for Research,Tabriz University Of Medical Sciences

#### Proportion provided by this source

100

#### Public or private sector

Private

#### Domestic or foreign origin

Domestic

#### Category of foreign source of funding

empty

#### Country of origin

## Type of organization providing the funding

Academic

+98 41 3553 9161

## Email

azimi@tbzmed.ac.ir

## Person responsible for general inquiries

### Contact

#### Name of organization / entity

Tabriz University of Medical Sciences

#### Full name of responsible person

Hamide Azimi

#### Position

Dermatologist/Associate professor

#### Latest degree

Specialist

#### Other areas of specialty/work

Dermatology

#### Street address

Dermatology ward, Sina Hospital, Azadi Ave.

#### City

Tabriz

#### Province

East Azarbaijan

#### Postal code

51386631357

#### Phone

+98 41 3553 9161

#### Email

azimi@tbzmed.ac.ir

## Person responsible for updating data

### Contact

#### Name of organization / entity

Tabriz University of Medical Sciences

#### Full name of responsible person

Hamide Azimi

#### Position

Dermatologist/Associate professor

#### Latest degree

Specialist

#### Other areas of specialty/work

Dermatology

#### Street address

Dermatology ward, Sina Hospital, Azadi Ave.

#### City

Tabriz

#### Province

East Azarbaijan

#### Postal code

51386631357

#### Phone

+98 41 3553 9161

#### Email

azimi@tbzmed.ac.ir

## Person responsible for scientific inquiries

### Contact

#### Name of organization / entity

Tabriz University of Medical Sciences

#### Full name of responsible person

Hamide Azimi

#### Position

Dermatologist/Associate professor

#### Latest degree

Specialist

#### Other areas of specialty/work

Dermatology

#### Street address

Dermatology ward, Sina Hospital, Azadi Ave. خیابان آزادی، بیمارستان سینا، بخش پوست

#### City

Tabriz

#### Province

East Azarbaijan

#### Postal code

51386631357

#### Phone

## Sharing plan

### Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

### Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

### Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

### Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

### Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

### Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

### Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available