

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 Jul 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 / cm². The amount of intralesional injection for 5-fluorouracil 250 ml / 5 ml would be 0.2 ml/cm². 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

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Name of organization / entity

Tabriz University of Medical Sciences

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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

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Tabriz

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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

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 / cm² (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 / cm²) 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

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Dermatology ward, Sina Hospital, Azadi Ave.

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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

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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

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

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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

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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