

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

A comparative study of the effect of intralesional triamcinolone acetonide and intralesional verapamil in the treatment of hypertrophic scars and keloids

Protocol summary

Summary

This study is a randomized double blind clinical trial on 50 patients with two or more keloids referred to Razi Hospital during 2015-16. Patients who will meet the criteria will included in the study using convenience sampling method and their scars will be randomly allocated using block randomization to receive intralesional injection of either verapamil or triamcinolone. Patients are included if they have two or more keloids under 5 years duration, without any history of prior treatment. Patients with systemic disorders and women during pregnancy and lactation will be excluded. Intralesional injections will performed. 1 milliliter was the maximum permissible injected volume of triamcinolone (concentration 40 milligram per milliliter) and verapamil (concentration 2.5 milligram per milliliter). The drugs are administered at 3 week intervals till the scar flattened or for a maximum period of 6 months. The patients will examined every 3 weeks till 6 months and will reevaluate after 3 months to check for any recurrence. The clinical assessment of the scar is based on the Vancouver Scar Scale and patient's satisfaction. The scale scores the scars on four parameters namely pigmentation, scar height, vascularity and pliability.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016010525871N1**

Registration date: **2016-06-17, 1395/03/28**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-06-17, 1395/03/28

Registrant information

Name

Pardis Sasani

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 21 8855 0680

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Tehran University of Medical Sciences

Expected recruitment start date

2016-04-02, 1395/01/14

Expected recruitment end date

2016-12-21, 1395/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparative study of the effect of intralesional triamcinolone acetonide and intralesional verapamil in the treatment of hypertrophic scars and keloids

Public title

Comparison of the effect of verapamil with corticosteroids in the treatment of keloids

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age over 18 years; two or more hypertrophic scars or keloids; total area less than 10 square centimeters; no previous treatment; scars under 5 years duration Exclusion criteria: Facial keloids; infection or ulcer, in or near the scar; pregnancy and lactation; patients with systemic illness like diabetes mellitus, mental disorder, cancer and cardiac disease; dark pigmented skin

Age

From **18 years** old to **100 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

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

Ethics committee of Tehran University of Medical sciences

Street address

Vice chancellor for research, No 23, Dameshgh Street, Felestin Avenue, Keshavarz Boulevard.

City

Tehran

Postal code**Approval date**

2016-03-09, 1394/12/19

Ethics committee reference number

IR.TUMS.REC.1394.2200

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

Keloid

ICD-10 code

L91.0

ICD-10 code description

Hypertrophic scar

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

Scar pigmentation

Timepoint

Before intervention, every 3 weeks for a period of 6 months, 3 months after the end of the intervention

Method of measurement

Observation and scoring based on Vancouver Scar Scale

2**Description**

Height of the scar

Timepoint

Before intervention, every 3 weeks for a period of 6 months, 3 months after the end of the intervention

Method of measurement

Using ruler and scoring based on Vancouver Scar Scale

3**Description**

Vascularity

Timepoint

Before intervention, every 3 weeks for a period of 6 months, 3 months after the end of the intervention

Method of measurement

visual inspection and the rate of refill after blanching and scoring based on Vancouver Scar Scale

4**Description**

Scar pliability

Timepoint

Before intervention, every 3 weeks for a period of 6 months, 3 months after the end of the intervention

Method of measurement

Palpation and scoring based on Vancouver Scar Scale

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

Patient's satisfaction

Timepoint

At the end of the study

Method of measurement

Asking the patients about any alternation in side effects of the keloids e.g. pain and pruritus

Intervention groups

1

Description

Intervention group: Intralesional injection of maximum 1 milliliter of verapamil hydrochloride (2.5 milligram per milliliter) every 3 weeks till the scar flattened or for a maximum period of 6 months. The injections will be made at 1 centimeter interval in the lesion with an insulin syringe and 30 gauge needle to achieve complete and evenly distributed blanching of the lesion at endpoint.

Category

Treatment - Drugs

2

Description

Control group: Intralesional injection of maximum 1 milliliter of triamcinolone acetonide (40 milligram per milliliter) every 3 weeks till the scar flattened or for a maximum period of 6 months. The injections will be made at 1 centimeter interval in the lesion with an insulin syringe and 30 gauge needle to achieve complete and evenly distributed blanching of the lesion at endpoint.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Razi Skin Hospital

Full name of responsible person

Pardis Sasani, Dermatology resident, Tehran University of Medical Sciences

Street address

Razi Skin Hospital, Vahdat e eslami Square, Vahdat e eslami Avenue.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor fpr research of Tehran University of Medical Sciences

Full name of responsible person

Alireza Firooz

Street address

415, Taleghani Avenue

City

Tehran

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Vice chancellor fpr research of Tehran University of Medical Sciences

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Pardis Sasani

Position

Doctor of Medicine/ Dermatology resident

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Robabeh Abedini

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Assistant Professor/Dermatologist

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

empty

Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty