Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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
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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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Full name of responsible person
Robabeh Abedini

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Assistant Professor/Dermatologist

Other areas of specialty/work

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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