Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jun 2026

comparing the efficacy of intralesional injection of verapamil combined with cryotherapy versus intralesional injection of triamcinolone combined with cryotherapy in keloids and hypertrophic scars

Protocol summary

Study aim

Comparing the efficacy of intralesional injection of verapamil combined with cryotherapy versus intralesional injection of triamcinolone combined with cryotherapy in keloids and hypertrophic scars.

Design

Parallel groups (two lesions in one individual), randomized, single blind, 15 individuals, 30 lesions, clinical trial

Settings and conduct

In each session, cryotherapy and Triamcinolone will be used for one lesion of patient and cryotherapy and Verapamil for other lesion of the same patient. it repeats every 3 weeks up to 8 sessions.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age between 18-70 years old; existence of at least two lesions in each individual. Exclusion crieria: any infections around or near lesions; pregnant women; history of previous intra lesional treatment; patient's lack of consent for having the lesion pictured.

Intervention groups

The lesion is sterilized by alcohol pad, then local anesthesia of the lesion with 2% Lidocaine ampule is performed by the ring block method. After anesthesia, cryotherapy is performed by spraying. Performing cryotherapy is in the form of continuous spraying from a distance of 1 cm from the top of the lesion for 20 seconds. After 1 minute, an ampule triamcinolone 40 mg / ml is injected into a lesion and another lesion is injected by verapamil (5 mg / 2ml). Triamcinolone is half and half diluted with lidocaine and injected with an insulin syringe of 27 gauge, maximum of 60 mg per session. Verapamil is injected with an insulin syringe of 27 gauge and maximum of 5.3 mg per session. Injections are done at multiple points, to the extent that the lesion is completely blanched.

Main outcome variables

Main outcome measures include keloid and the score of vancouver scar scale.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180327039151N1**
Registration date: **2018-05-18, 1397/02/28**
Registration timing: **retrospective**

Last update: **2018-05-18, 1397/02/28**
Update count: **0**

Registration date

2018-05-18, 1397/02/28

Registrant information

Name

Raya Mokhtari

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3624 6921

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mokhtarir@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-11-21, 1395/09/01

Expected recruitment end date

2017-11-22, 1396/09/01

Actual recruitment start date

2016-11-21, 1395/09/01

Actual recruitment end date
2017-11-22, 1396/09/01
Trial completion date
empty

Scientific title
comparing the efficacy of intralesional injection of verapamil combined with cryotherapy versus intralesional injection of triamcinolone combined with cryotherapy in keloids and hypertrophic scars

Public title
Comparing the efficacy of intralesional injection of verapamil combined with cryotherapy versus intralesional injection of triamcinolone combined with cryotherapy in keloids and hypertrophic scars
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Age 18-70 years old At least two lesions in each patient
Exclusion criteria:
Any infection around or near lesions Pregnant women History of previous intra lesional treatment Patient's lack of consent for having the lesion pictured
Age
From **18 years** old to **70 years** old
Gender
Both

Phase
3
Groups that have been masked

- Outcome assessor

Sample size
Target sample size: **15**
More than 1 sample in each individual
Number of samples in each individual: **2**
each individual has 2 keloids and hypertrophi scars
Actual sample size reached: **15**
More than 1 sample in each individual
Actual sample size in each individual: **2**
Each individual has 2 keloids and hypertrophi scars
Randomization (investigator's opinion)
N/A
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Outcome assessor: assessment of lesions by the co-worker is done. She is blind what medication is injected in each lesion.
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Shiraz University of Medical Sciences
Street address
Shiraz University of Medical Sciences, Zand st.
City
Shiraz
Province
Fars
Postal code
7134845794
Approval date
2017-12-02, 1396/09/11
Ethics committee reference number
IR.SUMS.MED.REC.1396.93

Health conditions studied

1

Description of health condition studied
Hypertrophic scar
ICD-10 code
L91.0
ICD-10 code description
hypertrophic scar, verapamil, triamcinolone

Primary outcomes

1

Description
Score of keloid in Vancouver scar scale
Timepoint
Before intervention and 3, 6, 9, 12, 15, 18, 21, 24 weeks after intervention
Method of measurement
Vancouver scar scale

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: triamcinolone, amp 40mg/ml, made in Exir company Iran, maximum 60mg in each session, intralesional injection, every 3 weeks, 8 sessions
Category
Treatment - Drugs

2

Description

Intervention group 2: verapamil, ampule 5 mg/2ml, made in Hexal company Germany, maximum 3.5 mg in each session, intralesional injection, every 3 weeks, 8 sessions

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Shahid Faghihi clinic

Full name of responsible person
Nasrin Saki

Street address
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7187711419

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Dr. Seied Basir Hashemi

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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
Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
Nasrin Saki

Position
assistant professor

Latest degree
Specialist

Other areas of specialty/work
Dermatology

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Person responsible for updating data

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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
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
Not applicable
Data Dictionary
Not applicable