

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Sep 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 criteria: any infections around or near lesions; pregnant women; history of previous intralesional 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

Email address

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 hypertrophied 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 hypertrophied 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
Zand Blvd, Shahid Faghihi clinic

City
Shiraz

Province
Fars

Postal code
7187711419

Phone
+98 71 3624 6921

Email
nasrinsa85@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shiraz University of Medical Sciences

Full name of responsible person
Dr. Seied Basir Hashemi

Street address
Faghihi hospital , Zand st , Shiraz, Iran

City
Shiraz

Province
Fars

Postal code
7134814336

Phone
+98 71 3230 5410

Email
hashemib@sums.ac.ir

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

Street address
Faghihi hospital ;Zand st

City
Shiraz

Province
Fars

Postal code
7187711419

Phone
+98 71 3624 6921

Email
nasrinsa85@yahoo.com

Person responsible for scientific 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

Street address
Faghihi Hospital ; Zand st

City
Shiraz

Province
Fars

Postal code
7187711419

Phone
+98 71 3624 6921

Email
nasrinsa85@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Raya Mokhtari
Position
Resident
Latest degree
Medical doctor
Other areas of specialty/work
Dermatology
Street address
Faghihi Hospital ; Zand st
City
Shiraz
Province
Fars
Postal code
7187711419
Phone
+98 71 3624 6921

Email
mokhtari.raya@gmail.com

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