

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 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 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**

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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

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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

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

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Nasrin Saki

**Position**

assistant professor

**Latest degree**

Specialist

**Other areas of specialty/work**

Dermatology

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**Contact**

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**Full name of responsible person**

Raya Mokhtari

**Position**

Resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Dermatology

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**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