

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jul 2026

Evaluation of the combined effect of intralesional injection of Triamcinolone and Verapamil in the treatment of post-surgery Keloid scars

Protocol summary

Registration timing: **prospective**

Study aim

Determining the combined effect of intralesional injection of triamcinolone and verapamil in the treatment of keloid scar after surgery

Last update: **2021-11-14, 1400/08/23**

Update count: **0**

Registration date

2021-11-14, 1400/08/23

Design

Clinical trial with control and intervention group, with parallel, randomized groups

Registrant information

Name

mohammadreza mobayen

Name of organization / entity

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Iran (Islamic Republic of)

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Settings and conduct

The group receiving triamcinolone without verapamil. The group receiving verapamil with triamcinolone (group 2) are randomly divided by Randomized Block method. Patients will go to Imam Reza Surgery Clinic of Poursina and Velayat Hospital and visiting by the surgeon will be investigated

Recruitment status

Recruitment complete

Funding source

Participants/Inclusion and exclusion criteria

In this study, the necessary information will be recorded in a questionnaire by the interviewer. Demographic information of patients (age, sex) as well as information about scars (size ,length, width, height), Percentage of flattening, redness of the lesion, pigmentation, flexibility,severity of itching and type of injection are recorded in their file. Other scars are also treated with triamcinolone according to routine protocols.

Expected recruitment start date

2021-11-22, 1400/09/01

Expected recruitment end date

2022-11-22, 1401/09/01

Intervention groups

Triamcinolone group (first group). Triamcinolone and verapamil group (group2)

Actual recruitment start date

empty

Actual recruitment end date

empty

Main outcome variables

Size (length, width, height) keloid ,Itching severity , Keloid flexibility

Trial completion date

empty

General information

Scientific title

Evaluation of the combined effect of intralesional injection of Triamcinolone and Verapamil in the treatment of post-surgery Keloid scars

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20210524051384N6**

Registration date: **2021-11-14, 1400/08/23**

Public title

Triamcinolone and Verapamil injection on Keloid scars

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

The Keloid scar should be at least 0.5 cm long and at most 10 cm At least 3 months will be passed since their surgery Patients are in the age range of 18 to 50 years consent Informed

Exclusion criteria:

Keloid scars with a duration of more than 12 months Patients with infection or any other disease in the vicinity of the wound Pregnant patients or those who plan to become pregnant in the near future Breastfeeding women Diabetic patients Patients with high blood pressure or heart problems People with chronic kidney disease or those who have had any abnormal changes in the CBC or liver tests Patients taking steroids or verapamil for other conditions Keloid scars of the head, face and neck

Age

From **18 years** old to **50 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **16**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, limited randomization will be used as a block randomization method to design patients into intervention and control groups. The latest allocation will prevent the direction from being detected in the blocks under consideration; the size of the blocks is considered random, with 2 or 4 It will use R software to generate random numbers using the Runif command.

Blinding (investigator's opinion)

Not 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 Guilan University of Medical Sciences

Street address

in front of 17 Shahrivar Hospital - St. - Shahid Siadati

St. -

City

Rasht

Province

Guilan

Postal code

4193713111

Approval date

2021-08-11, 1400/05/20

Ethics committee reference number

IR.GUMS.REC.1400.227

Health conditions studied

1

Description of health condition studied

Surgical keloid lesion

ICD-10 code

L91.0

ICD-10 code description

Hypertrophic scar

Primary outcomes

1

Description

length, Width, height of Keloid

Timepoint

Upon arrival and after each injection session until the lesion is completely flattened or up to 8 sessions

Method of measurement

Observer measurement by calibrated compass

2

Description

Redness of the lesion

Timepoint

Upon arrival and after each injection session until the lesion is completely flattened or up to 8 sessions

Method of measurement

Based on the description of the Oscar method

3

Description

Pigmentation

Timepoint

Upon arrival and after each injection session until the lesion is completely flattened or up to 8 sessions

Method of measurement

Based on the description of the Oscar method

4

Description

Flexibility

Timepoint

Upon arrival and after each injection session until the lesion is completely flattened or up to 8 sessions

Method of measurement

Based on the description of the Oscar method

5**Description**

Severe itching

Timepoint

Upon arrival and after each injection session until the lesion is completely flattened or up to 8 sessions

Method of measurement

Based on the description of the Oscar method

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: patients which are candidate of receiving triamcinolone (without verapamil), Injections into scars with Insulin gauge syringe No. 24 without local anesthesia and intralesional injection of triamcinolone acetone (Caspian khazar Triam Company) at a concentration of 40 mg / ml and a maximum dose of 2 mg per scar per session are performed.

Category

Treatment - Drugs

2**Description**

Group receiving triamcinolone and verapamil (group 2) Scar injections with insulin gauge syringe number 24 without local anesthesia and intralesional injection of verapamil (myland verapamil) 2.5 mg / ml with a maximum dose of 2.5 mg and triamcinolone At a concentration of 40 mg / ml and a maximum dose of 2 mg per scar per session.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Clinic of Poursina and Velayat Hospitals

Full name of responsible person

Mohammadreza Mobayen

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Poursina and Velayat Hospital, Parastar St, Namjo St, Rasht, Gilan, Iran

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Web page address**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Rasht University of Medical Sciences

Full name of responsible person

Dr. Mohammadreza Naghipour

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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

Rasht 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**

Rasht University of Medical Sciences

Full name of responsible person

Dr. Ramin Hadadi

Position

Assistant General Surgeon

Latest degree

Specialist

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity
Rasht University of Medical Sciences
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Position
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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

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available