Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

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

Protocol summary

Study aim
Determining the combined effect of intralesional injection of triamcinolone and verapamil in the treatment of keloid scar after surgery
Design
Clinical trial with control and intervention group, with parallel, randomized groups
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
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.
Intervention groups
Triamcinolone group (first group). Triamcinolone and verapamil group (group2)
Main outcome variables
Size (length, width, height) keloid ,Itching severity , Keloid flexibility

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20210524051384N6**
Registration date: **2021-11-14, 1400/08/23**
Registration timing: **prospective**

Last update: **2021-11-14, 1400/08/23**
Update count: **0**
Registration date
2021-11-14, 1400/08/23

Registrant information
Name
mohammadreza mobayen
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 13 3336 8540
Email address
maziar.mobayen@gmail.com

Recruitment status
Recruitment complete
Funding source

Expected recruitment start date
2021-11-22, 1400/09/01
Expected recruitment end date
2022-11-22, 1401/09/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

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

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 acetonide (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
Street address
Poursina and Velayat Hospital, Parastar St, Namjo St, Rasht, Gilan, Iran
City
Rasht
Province
Guilan
Postal code
41937-13194
Phone
+98 13 3332 5783
Fax
+98 13 3333 9842
Email
infogrtrc@gmail.com
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
Street address
Deputy of Research and Technology,In front of 17 Shahrivar Hospital, Namjo St.
City
Rasht
Province
Guilan
Postal code
4193713191
Phone
+98 13 3333 4936
Email
research@gums.ac.ir
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

General Surgery
Street address
Velayat Hospital, Namjo St.
City
Rasht
Province
Guilan
Postal code
4193713194
Phone
+98 13 3336 8540
Email
raminhadadi69@yahoo.com

Person responsible for scientific inquiries

Contact
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Dr.Mohammadreza Mobayen
Position
Fellowship in plastic surgery
Latest degree
Subspecialist
Other areas of specialty/work
General Surgery
Street address
Velayat Hospital, Namjo Street,
City
Rasht
Province
Guilan
Postal code
4193713191
Phone
+98 13 3336 8540
Email
Maziar.mobayen@gmail.com

Person responsible for updating data

Contact
Name of organization / entity
Rasht University of Medical Sciences
Full name of responsible person
Dr. Mohammadreza Mobayen
Position
Fellowship in Plastic Surgery
Latest degree
Subspecialist
Other areas of specialty/work
General Surgery
Street address
Velayat Hospital, Namjo St
City
Rasht
Province
Guilan
Postal code
4193713194
Phone
+98 13 3336 8540
Email
maziar.mobayen@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
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