Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of efficacy of combined intralesional steroid and cryotherapy versus intralesional steroid alone in treatment of keloid.

Protocol summary

Study aim
To compare the efficacy of intralesional triamcinolone acetonide and cryotherapy vs intralesional triamcinolone acetonide alone in treatment of keloid.

Design
Pragmatic ,community based ,parallel group ,not blinded ,randomized controlled trial consisting 64 patients divided in two group 32 in each group

Settings and conduct
This study will be conducted in the outpatient clinic of Dermatology PNS Shifa Hospital,Karachi, and will involve patients with keloid.

Participants/Inclusion and exclusion criteria
Inclusion criteria: Either gender, Having single or multiple keloids of size not more than 10 cm in the largest diameter. Patient between 12 to 60 years of age, Willing to sign informed consent Patients with infected keloid. Exclusion criteria: Co- existing inflammatory skin diseases. Unrealistic expectation or with psychiatric illnesses, Pre- existing bleeding disorders, Renal and hepatic disease. Lactating or Pregnant women. Immunodeficient patients. Diseases that react adversely to cold (Raynaud's disease, cryoglobulinemia ,cold urticaria) and with wound healing abnormalities

Intervention groups
64 Patients group A 32 will be received intralesional steroid and cryotherapy group B will received intralesional steroid alone

Main outcome variables
Change in vascularity , height ,pigmentation and pliability of scar in both groups. Overall treatment efficacy comparison between the group A (steroid with cryotherapy) and the group B (steroid only).

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20241028063523N2**
Registration date: **2024-11-12, 1403/08/22**
Registration timing: **registered_while_recruiting**

Last update: **2024-11-12, 1403/08/22**
Update count: **0**

Registration date
2024-11-12, 1403/08/22

Registrant information

Name
Atiya Rahman
Name of organization / entity
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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2024-11-04, 1403/08/14

Expected recruitment end date
2025-05-04, 1404/02/14

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Comparison of efficacy of combined intralesional steroid and cryotherapy versus intralesional steroid alone in treatment of keloid.

Public title
Comparison of efficacy of combined intralesional steroid and cryotherapy versus intralesional steroid alone in treatment of keloid.
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patient of either gender, Having single or multiple keloids of size not more than 10 cm Between 12 to 60 years of age Willing to sign informed consent
Exclusion criteria:
Patient with infected keloids Co existing inflammatory skin diseases Unrealistic expectations or with psychiatric illnesses Pre existing bleeding disorders. Renal disease and hepatic disease. Lactating / pregnant women. Immunodeficient patients , diseases that react adversely to cold (Raynaud's disease, cryoglobulinemia , cold urticaria) and with wound healing abnormalities will be excluded.
Age
From **12 years** old to **60 years** old
Gender
Both

Phase
4
Groups that have been masked
No information
Sample size
Target sample size: **64**
More than 1 sample in each individual
Number of samples in each individual: **32**
Diagnosis on the clinical basis and given intralesional steroid and cryotherapy versus intralesional steroid
Randomization (investigator's opinion)
Randomized
Randomization description
The keloid patients will randomly be divided into two groups by lottery method which will be administered two different treatment regimens. patient scar will be assessed by Vancouver scar scale.
Blinding (investigator's opinion)
Not blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
This will be a hospital based randomized control interventional study consisting of 64 patients (32 in each group).

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethical committee PNS shifa
Street address
DHA phase ll, PNS Shifa hospital near kala pul.
City
Karachi
Postal code
75500
Approval date
2024-04-04, 1403/01/16
Ethics committee reference number
ERC/2024/DERM/83

Health conditions studied

1

Description of health condition studied
Keloids
ICD-10 code
L73.0
ICD-10 code description
Keloids are dermal proliferations of fibrous tissue that often arise at sites of cutaneous injury and have significant impact on quality of life

Primary outcomes

1

Description
The primary outcome of the study will focus on changes in scar appearance, measured using the Vancouver Scar Scale. This scale evaluates several parameters, including pigmentation, pliability, height, and vascularity, providing a comprehensive assessment of treatment effectiveness. Additionally, patient-reported outcomes will be assessed through the Patient Scar Assessment Scale, specifically evaluating improvements in scar perception, including aspects such as pain, itching, color, stiffness, and thickness, as well as overall patient satisfaction with the appearance of their keloids.
Timepoint
Patient will be assessed at baseline and 4 weeks, 8 weeks , 12 weeks
Method of measurement
Vancouver scar scale and Patient Scar Assessment Scale

Secondary outcomes

1

Description
Secondary outcomes will be evaluated to enhance understanding of treatment efficacy. These include the recurrence rate of keloids, the time to noticeable improvement in scar characteristics, and the incidence of adverse effects in both groups. The study will also assess the impact of treatments on overall quality of life using standardized questionnaires, gather additional patient satisfaction scores, and analyze changes in scar

morphology through vancouver scar scale assessments taken before and after treatment.

Timepoint

Patient will be assessed at baseline 4 weeks , 8 weeks , 12 weeks

Method of measurement

Patient scar will be assessed by vancouver scar scale and subjective assessment noticed by patients themselves will be assessed by patient scar assessment scale .

Intervention groups

1

Description

There are no control group there two interventional group. 1. Group A will have 32 patients and the will be receive intralesional steroid treatment in conjunction with cryotherapy. In this group, patients will undergo cryotherapy using liquid nitrogen gas, applied until a freezing halo appears. This procedure will occur over two sessions. After the second thaw, patients will receive the intralesional steroid triamcinolone acetonide trade name (injection K-cort ampule manufacturer -pharma(pvt) Ltd at a concentration of 40 mg/ml, administered at a dosage of 0.1 ml per cm^2, not to exceed 1 ml per lesion at baseline and 4 weeks 8 weeks 12 weeks. Treatment responses for both groups will be evaluated using the Vancouver Scar Scale, along with subjective assessments from the patients. The response of treatment shall be entered in pre designed to asses the efficacy of two therapeutic agents . the data will be analyzed using SPSS version 23.

Category

Treatment - Drugs

2

Description

Intervention group: 2. Group B 32 will have and they will be receive only the intralesional steroid, triamcinolone acetonide trade name injection K-cort ampule manufacturer-pharma (Pvt.) Ltd, also at a concentration of 40 mg/ml, with the same dosing parameters as Group A (0.1 ml per cm^2, not exceeding 1 ml per lesion). at baseline and 4 weeks 8 weeks 12 weeks. Treatment responses for both groups will be evaluated using the Vancouver Scar Scale, along with subjective assessments from the patients. The response of treatment shall be entered in pre designed to asses the efficacy of two therapeutic agents . the data will be analyzed using SPSS version 23.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

PNS Shifa Hospital

Full name of responsible person

Dr Sadia D/O Sardar Ahmed Abbasi

Street address

DHA phase ll, PNS Shifa hospital, near kala pul.

City

Karachi

Postal code

75500

Phone

+92 21 48506540

Email

sadia.abbasi038@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Armed forces Hospital PNS Shifa karachi,Pakistan

Full name of responsible person

Dr Sadia D/O Sardar Ahmed Abbasi

Street address

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City

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Armed Forces

Proportion provided by this source

100

Public or private sector

Private

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

PNS Shifa

Full name of responsible person

Dr Sadia D/O Sardar Ahmed Abbasi

Position

Resident of dermatology

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

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Province

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Postal code

75500

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Person responsible for scientific inquiries

Contact

Name of organization / entity

PNS Shifa

Full name of responsible person

Dr Sadia D/O Sardar Ahmed Abbasi

Position

Resident of dermatology

Latest degree

Medical doctor

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Armed forces Hospital PNS Shifa Karachi,Pakistan

Full name of responsible person

Dr Sadia D/O Sardar Ahmed Abbasi

Position

Post graduate of Dermatology

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

DHA phase ll, PNS Shifa hospital, near Kala pul.

City

Karachi

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Postal code

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Phone

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sadia.abbasi038@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

Comparison of efficacy of combined intralesional steroid and cryotherapy versus intralesional steroid alone in the treatment of keloid.

When the data will become available and for how long

From may 2025, and it will be available lifelong

To whom data/document is available

It will be available for all healthcare professionals.

Under which criteria data/document could be used

Original article

From where data/document is obtainable

sadia.abbasi038@gmail.com

What processes are involved for a request to access data/document

Can contact via the above email ID.

Comments