Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of efficacy of carboxytherapy and intralesional injection of triamcinolone in the treatment of keloid: a randomized 2-split clinical trial

Protocol summary

Study aim

- Comparison of efficacy of carboxytherapy and intralesional injection of triamcinolone in the treatment of keloid lesions - Comparing the efficacy of carboxytherapy and triamcinolone intralesional injection in reducing the area of keloid and keloid thickness - Comparing the efficacy of carboxytherapy and intralesional injection of triamcinolone in terms of patient satisfaction in terms of response to treatment, level of pain and other side effects

Design

A randomized 2-split one-sided blind clinical trial, with a parallel group design of 17 patients. Coin tossing method was used for randomization.

Settings and conduct

This study is conducted in Arak University of Medical Sciences and is a single-blind randomized clinical trial. In each patient, the intervention and control groups will be selected randomly by tossing a coin, and in the control side, intralesional injection of triamcinolone will be done monthly, and in the intervention side, carboxytherapy will be done weekly. Except for the main project manager, other project managers do not know about the groupings, and data collection and evaluation is done by managers who are unaware of the project process.

Participants/Inclusion and exclusion criteria

- Informed consent to participate in the study - Age above 12 years - The presence of more than 2 keloids in the trunk or limbs and the distribution of lesions on both the right and left sides - Absence of pregnancy and breastfeeding - No smoking, alcohol and drug abuse - Absence of systemic diseases

Intervention groups

In the intervention group, carboxytherapy is performed weekly for 8 weeks. In the control group, triamcinolone injection is performed as a routine treatment of keloid lesions, at intervals of 4 weeks and for 2 months.

Main outcome variables

Reduction of colloid area; Reduction of colloid thickness; Patient satisfaction with treatment, pain level and other side effects

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20240614062129N1**
Registration date: **2024-10-10, 1403/07/19**
Registration timing: **registered_while_recruiting**

Last update: **2024-10-10, 1403/07/19**
Update count: **0**

Registration date

2024-10-10, 1403/07/19

Registrant information

Name

Kimiya Ahmadifar

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2024-09-15, 1403/06/25

Expected recruitment end date

2024-10-16, 1403/07/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of efficacy of carboxytherapy and intralesional injection of triamcinolone in the treatment of keloid: a randomized 2-split clinical trial

Public title

Comparison of efficacy of carboxytherapy and intralesional injection of triamcinolone in the treatment of keloid

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

People have informed consent to participate in the study Patients who are over 12 years old The presence of more than 2 keloid lesions in the trunk or limbs Distribution of lesions on both right and left sides and presence of at least one lesion on each side

Exclusion criteria:

Absence of pregnancy and breastfeeding No smoking, alcohol and drug abuse Not suffering from systemic diseases such as diabetes, kidney diseases, heart diseases, respiratory diseases, liver diseases, anemia, etc. Not having connective tissue diseases or genodermatosis

Age

From **12 years** old

Gender

Both

Phase

N/A

Groups that have been masked

- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **17**

Randomization (investigator's opinion)

Randomized

Randomization description

Coin toss method are used to determine the side of intervention and control. In this method, the back of the coin is considered as intervention and the face of the coin is considered as control. One side of the body is allocated to carboxytherapy by tossing a coin, and the other side to triamcinolone injection. During the study, the side of treatment with carboxytherapy or triamcinolone remains constant.

Blinding (investigator's opinion)

Single blinded

Blinding description

The present study is single-blind. Except for the first executive of the plan (Dr. Noushin Bagherani), who is fully aware of the treatment groups and promotes the treatment herself, the other executives of the plan do not know about the groupings. Uninformed facilitators examine the response to treatment, and data is collected by the student, who is unaware of the treatment group, and delivered to the principal facilitator of the plan. Patients are informed about the treatment method, but they are requested not to give any information about the treatment method.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Arak University of Medical Science

Street address

Department of Research and Technology, Arak University of Medical Sciences, Basij Square

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Postal code

3848176341

Approval date

2024-06-02, 1403/03/13

Ethics committee reference number

IR.ARAKMU.REC.1403.090

Health conditions studied

1

Description of health condition studied

Keloid lesions

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The area of keloid lesions

Timepoint

The area of keloid lesions is measured at the beginning of the study, before each carboxytherapy session and 2 weeks after the last carboxytherapy session.

Method of measurement

The area of the keloid lesions is measured with grid paper. For this purpose, we put transparent oil paper on

the desired lesion and mark its border. Then we transfer it to checkered paper with carbon paper and estimate the area of the lesion by counting the squares.

2

Description
Height of keloid lesions
Timepoint
The height of keloid lesions is measured at the beginning of the study, before each carboxytherapy session and 2 weeks after the last carboxytherapy session.
Method of measurement
The height of the target lesion in the thickest part in the peripheral area is calculated with the help of a ruler. For this purpose, with the help of a caliper, one tip of which is tangent to the base of the keloid and one tip is tangent to its surface, we determine the height of the lesion and adjust the distance between the two tips to the ruler.

3

Description
Patient satisfaction in terms of pain level
Timepoint
Patients' satisfaction in terms of pain level is evaluated during each carboxytherapy session
Method of measurement
The evaluation of pain is done with the Visual Analogue Scale.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: Carboxytherapy. In the intervention group, carboxytherapy is performed by injecting 2 cc of Co2 gas into the lesion for every square centimeter of colloid by the MEDAION carboxytherapy device, made in Iran, Nik Fanavaran Plasma Company. The gas is injected at a rate of half a cc per shot and at a temperature of 40 degrees Celsius. Injections will continue weekly for 8 weeks.
Category
Treatment - Other

2

Description
Control group: Intralesional injection of triamcinolone . In the control group, two units of triamcinolone acetonide diluted in lidocaine with a concentration of 20 mg/ml are injected from an insulin syringe at 4-week intervals.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
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Sponsors / Funding sources

1

Sponsor
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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
Arak 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

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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
Yes - There is a plan to make this available
Data Dictionary
Yes - There is a plan to make this available
Title and more details about the data/document
All data can be shared after de-identifying individuals. The data related to the main outcome of the study results will be published in general and without mentioning the names of the individuals.
When the data will become available and for how long
The access period begins after the results are printed.
To whom data/document is available
The data will be available to researchers working in academic, scientific institutions and researchers working in industry.
Under which criteria data/document could be used
All cases of using documents related to published data should be with reference to the original article and the authors of the article. Also, if there is a need to access the photos of the patients' lesions, written consent will be received from them and the patients' eyes will be covered so that they cannot be identified.
From where data/document is obtainable
Applicants can contact the authors of the article to receive the desired data at the email address of Dr. Noushin Bagherani at the following address. nooshinbagherani@yahoo.com
What processes are involved for a request to access data/document

After sending the request to the mentioned e-mail address, your request will be read and checked by Dr. Noushin Bagherani and will be shared with other authors of the article and then it will be answered, which will take approximately 14 days on average. it ends

Comments