

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Evaluation of the effectiveness of Carboxytherapy in treatment of eye dark circle

Protocol summary

Study aim

Effectiveness of carboxytherapy in treatment of dark circle under the eyes

Design

One group clinical trial consisted of 20 patients who enrolled between December and September 2018 and followed for 3 months.

Settings and conduct

This study was done among patients complained of darkening of the eye, attending skin clinic of Tehran Rasoul-e-Akram hospital. There wasn't blinding in the study.

Participants/Inclusion and exclusion criteria

Inclusion criteria: aged 20 to 50 years; male or female referring to the dermatology clinic for any reason with eye dark circle; Patients should have bilateral; symmetrical eye dark circle. Non inclusion criteria: Botox injections during the past 6 months; receiving treatment; history of systemic disease; history of keloid formation; infected site.

Intervention groups

For 20 patients with under eyes dark circles, Carboxytherapy was administered as following: intradermal injection of 10-20 cc CO₂ gas, rate: 20 cc/minute, angle: 15 degree, maximum 1 minute, duration: 4 sessions once a week. Patients followed 2 months later after last session with visioface camera.

Main outcome variables

Dark under eye circle

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191219045826N1**

Registration date: **2020-02-12, 1398/11/23**

Registration timing: **retrospective**

Last update: **2020-02-12, 1398/11/23**

Update count: **0**

Registration date

2020-02-12, 1398/11/23

Registrant information

Name

aboozar shafiei

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 4224 0028

Email address

dr.a.shafeie55@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-01-24, 1397/11/04

Expected recruitment end date

2019-04-14, 1398/01/25

Actual recruitment start date

2019-01-29, 1397/11/09

Actual recruitment end date

2019-04-14, 1398/01/25

Trial completion date

2019-04-14, 1398/01/25

Scientific title

Evaluation of the effectiveness of Carboxytherapy in treatment of eye dark circle

Public title

Effect of co₂ gas in treatment of eye dark circle

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Symmetrical eye dark circle Bilateral eye dark circle Age of

20 to 50 years old

Exclusion criteria:

Give treatment History of keloid formation Have systemic disease Botax injection since 6/m ago

Age

From **20 years** old to **50 years** old

Gender

Both

Phase

4

Groups that have been masked

No information

Sample size

Target sample size: **20**

Actual sample size reached: **20**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Single

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

Shahid Faghihi hospital, Zand street, Shiraz

City

Shiraz

Province

Fars

Postal code

۷۱۳۴۸۴۴۱۱۹

Approval date

2019-01-25, 1397/11/05

Ethics committee reference number

IR.SUMS.MED.REC.1397.342

Health conditions studied

1

Description of health condition studied

Dark under eye circles

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Dark under eye circles

Timepoint

Before gaz injection then 2 month after last injection

Method of measurement

visioface delta E scale

Secondary outcomes

empty

Intervention groups

1

Description

Twenty consecutive eligible patients with DECs selected to enter the study and received carboxytherapy as injection of once weekly intradermally 10 to 20 cc of CO₂ gas at a rate of 20 cc per minute with angle of 15 degree to the orbital skin, for maximum 1 minute (usually few seconds), to appear skin swelling, erythema or occurrence of pain. The total number of therapies was 4 sessions with 1 week interval and patients followed 2 month later after last session of carboxytherapy. Patients were photographed by VisioFace® 1000 D - Courage - Khazaka Electronic. The data was recorded as quantitative values based on ΔE (the difference between pigmentation in different parts of pigmented orbit skin (lateral and middle and medial) with adjacent normal skin of extra-orbital area), which was calculated by VisioFace device. The name of carboxytherapy was carbocure and manufactured by ronak tajhiz ara in iran .Concentration of co₂ gas was 99% .

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Rasul-e Akram Hospital

Full name of responsible person

Elham Behrangi

Street address

Hazrate Rasoole Akram Hospital, Niayesh street, Satarkhan street

City

Tehran

Province

Tehran

Postal code

1445613131

Phone

+98 21 6651 5001

Email

Hrmc@iums.ac.ir

Web page address

Https://hrmc@iums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Yones Ghasemi

Street address

Shiraz University of Medical Sciences, Namazi square,
Zand street, Shiraz

City

Shiraz

Province

Fars

Postal code

۷۱۳۳۶ - ۷۱۳۴۸

Phone

+98 71 3230 5410

Fax

Email

Info@sums.ac.ir

Web page address

Http://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

Aboozar Shafiei

Position

Dermatology resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

Before reaching Imam Hossein square, Zand street

City

Shiraz

Province

Fars

Postal code

۷۱۳۴۸۴۵۷۹۴

Phone

+98 71 4224 0028

Fax

Email

dr.a.shafeie55@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Aboozar Shafiei

Position

Dermatology resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

Street address

Before reaching Imam Hossein square, Zand street

City

Shiraz

Province

Fars

Postal code

7134845794

Phone

+98 71 4224 0028

Fax

Email

dr.a.shafeie55@gmail.com

Web page address

https://sums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Aboozar Shafiei

Position

Dermatology resident

Latest degree

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Dermatology

Street address

Before reaching Imam Hossein square, Zand street

City

Shiraz

Province

Fars

Postal code

٧١٣٤٨٢٥٧٩٤

Phone

+98 71 4224 0028

Fax**Email**

dr.a.shafeie55@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