

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 May 2026

Evaluation of the effects of carboxytherapy in treatment of periorbital dark circles: A limited phase-3 study

Protocol summary

Study aim

Evaluation of carboxy therapy efficacy of DEC

Design

The study population is selected from those who refer to the skin clinic. Sampling was randomly selected based on the inclusion criteria from clients with a complaint of nearsightedness and the approval of a dermatologist and the acceptance of informed consent to participate in the project. Phase III is limited to 31 patients.

Settings and conduct

Dermatology Clinic TUMS BRANCH OF ACECR

Participants/Inclusion and exclusion criteria

The cause of darkness is not due to weight loss or anatomical problems in this area. - Age between 20 and 50 years, including men and women, with a complaint of dark circles around the eyes and a dermatologist's confirmation - Do not have a history of cancer - Patients should not be pregnant or breastfeeding - Do not have uncontrolled or acute cardiovascular diseases (uncontrolled blood pressure). - Do not have acute respiratory diseases and pulmonary embolism that occurred recently - Do not have blood coagulation problems (such as hemophilia). - There should be no active infection in the area - Don't have connective tissue diseases - Uncontrolled diabetes - Do not have a history of keloid - No botox injection in the last month
Exclusion criteria: If any of the conditions for entering the study are not met during four sessions of carboxytherapy for patients (an active infection develops, the mentioned diseases occur during this period, the patient becomes pregnant, etc.), the patient will be excluded from the study.

Intervention groups

27 patients with blepharitis and dermatological confirmation

Main outcome variables

The main result is the reduction of darkness around the eyes in different treatment sessions.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150822023706N3**

Registration date: **2023-02-05, 1401/11/16**

Registration timing: **retrospective**

Last update: **2023-02-05, 1401/11/16**

Update count: **0**

Registration date

2023-02-05, 1401/11/16

Registrant information

Name

Afshan Shirkavand

Name of organization / entity

Medical Laser research center

Country

Iran (Islamic Republic of)

Phone

+98 21 6646 2915

Email address

ashirkavand@alumnus.tums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2022-08-23, 1401/06/01

Expected recruitment end date

2022-12-22, 1401/10/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effects of carboxytherapy in treatment of periorbital dark circles: A limited phase-3 study

Public title

Evaluation of the effects of carboxytherapy in treatment of periorbital dark circles: A limited phase-3 study

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

no weight loss 20-50 years no cancer history no pregnant and feeding no hypertension no respiratory syndromes no coagulant disorders no active infections no tissue transplantation no uncontrolled diabet no keloid history no botox

Exclusion criteria:

exist of any inclusion criteria

Age

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

Gender

Both

Phase

2

Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser
- Data and Safety Monitoring Board

Sample size

Target sample size: **27**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

two dermatologists evaluate VAS changes of DEC's as blinded evaluation.

Placebo

Not used

Assignment

Single

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Motamed INSTITUTE , ACECR

Street address

No.17 Nazari street

City

Tehran

Province

Tehran

Postal code

1315795613

Approval date

2021-11-13, 1400/08/22

Ethics committee reference number

IR-ACECR-IBCRC-REC.1400.011

Health conditions studied

1

Description of health condition studied

dark eye circle

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Darkness scores at the end of treatment or in different sessions

Timepoint

Before treatment - after the first, second and third session

Method of measurement

Based on VAS (Visual Analogue Scale) satisfaction criteria

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: carboxy therapy

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

yara institute

Full name of responsible person

Dr.Seyed Mehdi Tabaie

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Yara institute
Full name of responsible person
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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
Yara institute
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
YARA institute
Full name of responsible person
Dr Seyed Mehdi Tabaie
Position
associate Professor
Latest degree
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Other areas of specialty/work
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Person responsible for scientific inquiries

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Person responsible for updating data

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Email

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

private data of the patients

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

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

Not applicable

Data Dictionary

Not applicable