

Clinical Trial Protocol

Iranian Registry of Clinical Trials

26 Jul 2026

Evaluation of carboxy therapy efficacy with NB-UVB phototherapy compared with NB-UVB phototherapy alone in patients with vitiligo

Protocol summary

Study aim

Determination of efficacy of carboxy therapy with NB-UVB phototherapy compared with NB-UVB phototherapy alone in patients with vitiligo referred to Kerman Afzalipour Hospital

Design

A randomized controlled clinical trial with 30 vitiligo patients selected from patients referring to Afzalipour Hospital, Ba'athat Clinic and Dermatology Clinic. Sampling is available in this study, double blind

Settings and conduct

The patient with vitiligo is treated at Afzalipour Hospital three times a week according to the protocol. In each patient, one lesion undergoes carboxy therapy and carboxy treatment is performed weekly for 16 weeks. The study is a double-blind study and the patient and evaluator of treatment response have no information about treatment type.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Vitiligo patient with at least 18 years of age, no treatment for 3 months before enrollment, bilateral lesions on both sides Exclusion criteria: photosensitive diseases, segmental vitiligo, autoimmune disease and other treatments, positive Cobner history, previous history of colloid formation, pregnancy, lactation, malignant disease, skin infection in situ, ischemic disease Heart, acute embolism, thrombophlebitis, gangrene, renal failure, hypertension, fever, history of stroke, administration of carbonic anhydrase inhibitors (acetazolamide, diclofenac) and decreased plasma protein levels in chronic liver failure

Intervention groups

The patient is treated with phototherapy three times a week according to the protocol. In each patient, one lesion undergoes carboxy therapy and carboxy treatment is performed weekly for 16 weeks. Control group: Phototherapy is performed three times a week in patients with sympathetic vitiligo lesions.

Main outcome variables

Rate of recovery Complication rate Pigmentation type

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190517043610N1**

Registration date: **2020-02-15, 1398/11/26**

Registration timing: **registered_while_recruiting**

Last update: **2020-02-15, 1398/11/26**

Update count: **0**

Registration date

2020-02-15, 1398/11/26

Registrant information

Name

fatemeh yazdanpanah

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 34 3132 8000

Email address

f.yazdanpanah86@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-06-22, 1398/04/01

Expected recruitment end date

2020-02-20, 1398/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Evaluation of carboxy therapy efficacy with NB-UVB phototherapy compared with NB-UVB phototherapy alone in patients with vitiligo

Public title
The Effect of Carboxy Therapy on Vitiligo Treatment

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
Vitiligo disease with sympathetic involvement on both sides of the body
Exclusion criteria:
Photosynthetic Diseases Segmental vitiligo Autoimmune Disease Use of other vitiligo treatments such as topical corticosteroids and topical calcineurin. Patient with positive Kobner history and previous history of colloid formation pregnancy and lactation malignancy Infection at the injection site Severe ischemic heart disease, acute embolism, thrombophlebitis, gangrene, history of stroke renal failure hypertension Use of carbonic anhydrase inhibitors (acetazolamide, diclofenac) Decreased plasma protein levels in chronic hepatic failure

Age
From **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked

- Participant
- Outcome assessor

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description
Evaluation of patients by an evaluating physician who has no treatment information is performed at the end of treatment and patients are unaware of the type of treatment.

Placebo
Not used

Assignment
Single

Other design features

Secondary Ids
empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of kerman University of Medical Sciences
Street address
Emam khomeini blvd,kerman town
City
Kerman
Province
Kerman
Postal code
7616913911
Approval date
2019-07-07, 1398/04/16
Ethics committee reference number
IR.KMU.AH.REC.1398.033

Health conditions studied

1

Description of health condition studied
Vitiligo
ICD-10 code
L80
ICD-10 code description
Vitiligo

Primary outcomes

1

Description
Skin pigmentation of lesions
Timepoint
Before treatment and one month, two months, three months and four months after treatment
Method of measurement
Questionnaire designed by the researcher

Secondary outcomes
empty

Intervention groups

1

Description
The patient will be treated with phototherapy three times a week according to the protocol. In each patient, one lesion undergoes carboxy therapy and carboxy therapy is performed weekly for 16 weeks. The rate of gas infusion is 50 cc / min and the total amount of gas injected in each lesion is 3 cc and the median time of each session is 5 to 8 minutes.
Category
Treatment - Devices

2

Description

Control group: Patient with bilateral vitiligo lesions treated with protocol three times a week according to protocol

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Afzalipour Hospital, Ba'ath Clinic

Full name of responsible person

Saiede Farajzade

Street address

Emam Khomeini Blvd, Afzalipour Hospital

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7616913911

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+98 34 3132 8000

Email

Safaderm@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Abbas Pardakhti

Street address

The beginning of the axis of the seven gardens of Alavi campus of Kerman University of Medical Sciences

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abapardakhty@kmu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Kerman 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

Kerman University of Medical Sciences

Full name of responsible person

Saiede Farajzade

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

Dermatology

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Saiede Farajzade

Position

Professor

Latest degree

Subspecialist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Kerman University of Medical Sciences

Full name of responsible person

Fateme Yazdanpanah

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Dermatology

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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