

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

The effect of high concentration CO₂-enriched water on sensory neuropathy in patients with diabetes

Protocol summary

Study aim

evaluate the effects of carboxytherapy on the signs and symptoms of sensory neuropathy in diabetic patients.

Design

Sample Size: 50 patients Study population: Patients with diabetic sensory neuropath Calculation the sample size: Due to the pilot nature of the study and the facilities of the research team Sampling Method: Targeted Data collection technique: Observation and interview This study was performed in a pre-and post-intervention design. Repeated measures linear model (repeated measures ANOVA) or Friedman test was used to analyze data and compare the outcomes between the study groups at three follow-up stages (for the data fulfilling normal distribution). Statistical analysis was performed using IBM SPSS software version 16.

Settings and conduct

Fifty patients entered the study, each participant received highly concentrated CO₂-enriched water once a day for 15 days and then once a week for three months. The prevalence of neuropathy-related signs and symptoms was assessed using the Michigan Neuropathy Screening Instrument (MNSI) and the Visual Analogue Scale (VAS) questionnaires, before, after 15 sessions and after 3 months.

Participants/Inclusion and exclusion criteria

Patients with diabetic sensory neuropathy referring to the endocrinology clinic of Loghman e Hakim Hospital, who have been suffering from type 1 or type 2 diabetes for more than 5 years. Non-entry conditions: The patient's unwillingness to participate in the study Diabetic motor neuropathy Age below 20 and above 70 years Having neuropathy due to other causes of neuropathy

Intervention groups

The patients placed their feet in a CO₂-enriched water bath (39°C, the concentration of 1100 ppm)

Main outcome variables

CO₂-enriched water; Score of Michigan Neuropathy

Screening Questionnaire in three follow-up periods; Intensity of numbness, burning pain, muscle cramp in three follow-up periods

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20220814055686N1**

Registration date: **2023-03-06, 1401/12/15**

Registration timing: **retrospective**

Last update: **2023-03-06, 1401/12/15**

Update count: **0**

Registration date

2023-03-06, 1401/12/15

Registrant information

Name

Safoura Alsadat Hoseini

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 86 4634 2056

Email address

safura.b.hoseini@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-04-09, 1398/01/20

Expected recruitment end date

2020-03-10, 1398/12/20

Actual recruitment start date

2019-05-05, 1398/02/15

Actual recruitment end date

2020-02-04, 1398/11/15
Trial completion date
 2020-06-19, 1399/03/30

Scientific title
 The effect of high concentration CO₂-enriched water on sensory neuropathy in patients with diabetes

Public title
 The effect of high concentration CO₂-enriched water on sensory neuropathy in patients with diabetes

Purpose
 Treatment

Inclusion/Exclusion criteria
Inclusion criteria:
 diabetic patient with diabetic sensory neuropathy
Exclusion criteria:
 Unwillingness to participate in the study Age of <20 and >70 years The diagnosis of diabetic motor neuropathy Neuropathy secondary to other causes

Age
 From **20 years** old to **70 years** old

Gender
 Both

Phase
 N/A

Groups that have been masked
No information

Sample size
 Target sample size: **50**
 Actual sample size reached: **50**

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 Shahid Beheshti University of Medical Sciences
Street address
 No. 2, Arabi Ave., Velenjak St
City
 Tehran
Province
 Tehran
Postal code

1985717443
Approval date
 2018-10-27, 1397/08/05
Ethics committee reference number
 IR.SBMU.MSP.REC.1397.805

Health conditions studied

1

Description of health condition studied

Diabetic sensory neuropathy

ICD-10 code

E08.40

ICD-10 code description

Diabetes mellitus due to underlying condition with diabetic neuropathy, unspecified

Primary outcomes

1

Description

Diabetic Sensory Neuropathy

Timepoint

At the beginning of the study, after 15 sessions and after three months of using CO₂-enriched water

Method of measurement

Michigan Neuropathy Screening Instrument (MNSI) and the Visual Analogue Scale (VAS) questionnaires

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: First, the Michigan Neuropathy Screening Instrument (MNSI) (10) and the Visual Analogue Scale (VAS) questionnaires were completed by patients. Then, patients placed their feet in a CO₂-enriched water bath (39°C, the concentration of 1100 ppm) daily for 15 days and 30 minutes each time. After completing the sessions, patients were re-evaluated and filled out the questionnaires again to record possible changes. Sessions were set once a week for three months (30 minutes at each session), and then the patients underwent the same examinations again to detect any change in patient's symptoms.

Category

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center

Loghman e Hakim hospital

Full name of responsible person

Doctor Saied Kalbasi

Street address

Makhsous Ave., Lashkar Squ., Loghman e Hakim Hospital

City

Tehran

Province

Tehran

Postal code

1333635445

Phone

+98 21 5541 9005

Fax

Email

loghman.hospital@sbmu.ac.ir

Web page address

<https://lhmc.sbmu.ac.ir>

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Doctor Afshin Zarghi

Street address

No. 2, Arabi Ave., Velenjak St

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 2243 9780

Email

info@sbmu.ac.ir

Web page address

<http://research.sbmu.ac.ir>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Saeid Kalbasi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Endocrinology

Street address

Makhsous Ave., Lashkar Squ., Loghman e Hakim Hospital

City

Tehran

Province

Tehran

Postal code

1333635445

Phone

+98 21 5541 9005

Email

saeid_kalbasi@yahoo.com

Web page address

<https://lhmc.sbmu.ac.ir>

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Saeid Kalbasi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

Makhsous Ave., Lashkar Squ., Loghman e Hakim Hospital

City

Tehran

Province

Tehran

Postal code

1333635445

Phone

+98 21 5541 9005

Email

saeid_kalbasi@yahoo.com

Web page address

<https://lhmc.sbmu.ac.ir>

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Saeid Kalbasi

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

Street address

Makhsous Ave., Lashkar Squ., Loghman e Hakim
Hospital

City

Tehran

Province

Tehran

Postal code

1333635445

Phone

+98 21 5541 9005

Email

saeid_kalbasi@yahoo.com

Web page address

<https://lhmc.sbmu.ac.ir>

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

Questionnaires filled by patients are for sharing.

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

Only for researchers working in academic and scientific institutions

Under which criteria data/document could be used

There is no limit

From where data/document is obtainable

Refer to Loghman e Hospital. Dr. Saeid Kalbasi. Number:
0098 21 5541905

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

It takes about one to two weeks

Comments