

Clinical Trial Protocol

Iranian Registry of Clinical Trials

05 Jul 2026

Comparison of the effectiveness of Ozone therapy with conventional therapy in improving visual evoked potentials parameters in diabetic patients

Protocol summary

Study aim

Evaluating the effectiveness of Ozone therapy in improving Visual Evoked Potentials (VEP) parameters in diabetic patients

Design

A pragmatic, single-centre, parallel-group, nonblinded, phase 2 randomised controlled trial which will be conducted on 60 DM patients and the patients will be followed up for 3 months.

Settings and conduct

Diabetic patients who visit Baqiyatallah clinic will be randomly allocated into two groups. After obtaining written informed consent for the oxygen-ozone therapy, patients of the treatment group will undergo ozone therapy (Major and Minor Autohemotherapy) twice weekly for 20 sessions in addition to standard conventional treatments. Patients of the control group will just undergo standard conventional treatments. VEP will be recorded in all patients at baseline and monthly thereafter for 3 months. HbA1C levels are measured before and after the intervention in all patients.

Participants/Inclusion and exclusion criteria

Patients who have been diagnosed with Diabetes Mellitus (DM) will be recruited unless having hypersensitivity to ozone or having abnormal coagulation or thyroid function tests

Intervention groups

Patients of the treatment group will undergo a cycle of systemic oxygen-ozone therapy in addition to the standard conventional therapy such as metabolic control. Patients of the control group will not receive any treatments other than the standard conventional therapy.

Main outcome variables

HbA1C (Pre-treatment and Post-treatment); P100 wave latency and amplitude (at baseline and monthly thereafter until 3 months)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191125045492N1**

Registration date: **2019-11-27, 1398/09/06**

Registration timing: **prospective**

Last update: **2019-11-27, 1398/09/06**

Update count: **0**

Registration date

2019-11-27, 1398/09/06

Registrant information

Name

Ali Sarrafzadeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 13 3324 7683

Email address

ali_sarrafzadeh@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-20, 1398/09/29

Expected recruitment end date

2020-01-20, 1398/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effectiveness of Ozone therapy with conventional therapy in improving visual evoked potentials parameters in diabetic patients

Public title

Comparison of the effectiveness of Ozone therapy with conventional therapy in the improvement of visual pathways function in diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients who have been diagnosed with Diabetes Mellitus

Exclusion criteria:

Patients with hypersensitivity to ozone Patients with abnormal thyroid function tests Patients with abnormal coagulation tests Patients with G6PD deficiency Pregnant or lactating women

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: 60

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, the individuals will be randomly allocated into two groups (Treatment and Control) by using the block randomization method. The procedure of randomization will be carried out by using the SPSS software and the block size will be 4. Allocation concealment will be carried out.

Blinding (investigator's opinion)

Not blinded

Blinding description

Placebo

Not used

Assignment

Factorial

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Baqiyatallah University of Medical Sciences

Street address

No. 2, South Sheikh Bahaei Ave.

City

Tehran

Province

Tehran

Postal code

1435912345

Approval date

2019-05-21, 1398/02/31

Ethics committee reference number

IR.BMSU.REC.1398.043

Health conditions studied

1

Description of health condition studied

Diabetes Mellitus

ICD-10 code

E11

ICD-10 code description

Type 2 diabetes mellitus

Primary outcomes

1

Description

VEP P100 wave amplitude

Timepoint

before intervention and 1, 2, 3 months after the start of intervention

Method of measurement

VEP measurement using visual electrophysiology device

2

Description

VEP P100 wave latency

Timepoint

before intervention and 1, 2, 3 months after the start of intervention

Method of measurement

VEP measurement using visual electrophysiology device

Secondary outcomes

1

Description

Hemoglobin A1C

Timepoint

3 months after the start of intervention

Method of measurement

lab kit

Intervention groups

1

Description

Intervention group:

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Ozonotherapy Research Center, Baqiyatallah
University of Medical Sciences

Full name of responsible person

Morteza Izadi

Street address

No. 2, South Sheikh Bahaei Ave.

City

Tehran

Province

Tehran

Postal code

1435912345

Phone

+98 21 8804 6515

Email

ali_sarrafzadeh@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Dr. Gholamhosein Alishiri

Street address

Vanak Square, Mullasadra Street, South Sheikh
Bahaei Ave.

City

Tehran

Province

Tehran

Postal code

1435916471

Phone

+98 21 8755 5250

Email

R.bmsu@yahoo.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Bagheiat-allah 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

Bagheiat-allah University of Medical Sciences

Full name of responsible person

Ali Sarrafzadeh

Position

General Practitioner on military service

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

No. 21, Ahmadzade Ave., Ansari Blvd.

City

Rasht

Province

Guilan

Postal code

4153786864

Phone

+98 13 3324 7683

Fax**Email**

ali_sarrafzadeh@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

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Person responsible for updating data

Contact

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ali_sarrafzadeh@yahoo.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