Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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)

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+98 13 3324 7683

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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

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Ozonetherapy Research Center, Baqiyatallah University of Medical Sciences

Full name of responsible person
Morteza Izadi

Street address
No. 2, South Sheikh Bahaei Ave.

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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.

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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
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
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Person responsible for updating data

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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