

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Effect of galvanic vestibular stimulation on reduction of blood glucose level and HbA1c of type 2 diabetic patients

Protocol summary

Study aim

Determine the Effects of Vestibular Galvanic Stimulation (GVS) on Blood Glucose Control in Patients with Type 2 Diabetes Mellitus

Design

Clients are selected according to inclusion and exclusion criteria and then we will divide them in two equal groups of 16 people by random blocking method. The sample size for each group will be 16 people .

Settings and conduct

People with diabetes mellitus referred to Zahedan Diabetes Clinic located at Bou-ali Hospital, Zahedan. First, each person participating in the study will receive a fasting blood glucose test and hemoglobin A1C baseline. The stimulator was designed using a vestibular galvanic stimulation. At the beginning of each week, blood sampling will be done by a laboratory technician to check blood sugar levels before and after stimulation. At the end of the 12th week, we will also have a sample to measure blood glucose and hemoglobin A1C. Glucose and hemoglobin A1C of the intervention group is evaluated again one month after the end of the stimulation presentation.

Participants/Inclusion and exclusion criteria

Patients who have been diagnosed with diabetes for at least 6 months and receive the same therapeutic treatment of blood glucose and their hemoglobin A1C is not more than 9.5% .

Intervention groups

Each person receives stimulation three times a week in three different days. Each time the stimulation is set to 20 minutes, its flow is set at the threshold of the individual. The Stochastic Stream uses random frequencies from 1 to 30 Hz. In control group electrodes placed same as other group but the current will be zero.

Main outcome variables

blood glucose level and HbA1c

General information

Reason for update

Acronym

GVS

IRCT registration information

IRCT registration number: **IRCT20180228038904N1**

Registration date: **2018-06-30, 1397/04/09**

Registration timing: **retrospective**

Last update: **2018-06-30, 1397/04/09**

Update count: **0**

Registration date

2018-06-30, 1397/04/09

Registrant information

Name

Aghil Absalan

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 2243 6092

Email address

aghilabsalan@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-21, 1397/02/01

Expected recruitment end date

2018-06-22, 1397/04/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of galvanic vestibular stimulation on reduction of blood glucose level and HbA1c of type 2 diabetic patients

Public title

Effect of galvanic vestibular stimulation on diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Confirmation of Type 2 Diabetes Mellitus by Endocrinologist Patients who have been diagnosed with diabetes for at least 6 months and receive Metformin The hemoglobin A1C is between 7.5 and 9.5% Collaboration on the exam

Exclusion criteria:

Having digestive and balance disorders Having systemic diseases use of non-diabetic drugs that affect blood glucose

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant

Sample size

Target sample size: 48

Randomization (investigator's opinion)

Randomized

Randomization description

They are selected according to inclusion and exclusion criteria and then we will divide them in two equal groups of 16 people by random blocking method. The control group will receive the false stimulus or sham and the intervention group will receive the GVS. In this method, control group and intervention group named as A and B respectively. Six statuses (AABB, ABAB, ABBA, BBAA, BABA, and BAAB) are written on paper and in the first stage one of them will be selected randomly. Four first patients will be grouped according to selected status. This trend continues 8 times

Blinding (investigator's opinion)

Single blinded

Blinding description

The control group receiving the false stimulus or sham and the intervention group receiving the GVS are not aware about receiving true stimulation.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of University of Social Welfare and Rehabilitation Sciences

Street address

Velenjak, Daneshjoo Blvd, Koodakyar ave.

City

Tehran

Province

Tehran

Postal code

۱۹۸۵۷۱۳۸۳۴

Approval date

2017-11-11, 1396/08/20

Ethics committee reference number

IR.USWR.REC.1396.249

Health conditions studied

1

Description of health condition studied

Type 2 diabetes

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes

1

Description

Blood glucose level

Timepoint

Blood glucose at beginning of study, first day of every week, last day of 12th week, one month after the end of stimulation. and of stimulation.

Method of measurement

blood sampling by the laboratory

2

Description

HbA1C

Timepoint

HbA1C at beginning of study, last day of 12th week, one month after the end of stimulation.

Method of measurement

blood sampling by the laboratory

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Each person receives galvanic vestibular stimulation three times a week in three different days. Each time the stimulation is set to 20 minutes, its flow is set at the threshold of the individual. The Stochastic Stream uses random frequencies from 1 to 30 Hz.

Category

Treatment - Other

2

Description

Control group (Sham): Each person receives galvanic vestibular stimulation three times a week in three different days. Each time the stimulation is set to 20 minutes . The current is zero

Category

Treatment - Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Diabetes center,Bu-Ali hospital,Zahedan

Full name of responsible person

Dr. MahmmoudAli Keykhaei

Street address

Amiralmomenin Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Dr.Amir Masoud Arab Loodaricheh

Street address

University of Social Welfare and Rehabilitation Sciences,Koodakyar Ave,Daneshjoo Blvd,Velenjak

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Email

am.arabloo@uswr.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

University of social welfare and rehabilitation 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

University of social welfare and rehabilitation sciences

Full name of responsible person

Dr. Younes Lotfi

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work

Ear, Nose, and Throat

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Person responsible for scientific inquiries

Contact

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Aghil Absalan

Position

دانشجو دکتری

Latest degree

Master

Other areas of specialty/work

Audiology

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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

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Yes - There is 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

Title and more details about the data/document

Individual data after being unidentifiable

When the data will become available and for how long

after publication

To whom data/document is available

researchers

Under which criteria data/document could be used

It is only allowed to mention the results

From where data/document is obtainable

aghil absalan aghilabsalan@zaums.ac.ir

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

Up to one month after receiving the email

Comments

Person responsible for updating data

Contact

Name of organization / entity

University of social welfare and rehabilitation sciences

Full name of responsible person

Aghil Absalan

Position

دانشجو دکتری

Latest degree

Master

Other areas of specialty/work

Audiology

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