

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Jun 2026

Effect of Neuromuscular Electrical Stimulation on serum glucose level condition in Children and Adolescents with Type 1 Diabetes Mellitus

Protocol summary

Study aim

Effect of neuromuscular electrical stimulation on serum glucose level condition, HbA1c and total daily dose of insulin in children and adolescents with type 1 diabetes mellitus

Design

Single group before-after clinical trial

Settings and conduct

Children and adolescents with type 1 diabetes referred to the endocrinology clinic of Amirkola Children's Hospital are included in the study according to the inclusion criteria.

Participants/Inclusion and exclusion criteria

Children and adolescents with type 1 diabetes, 7-18 years and a history of at least one year from onset

Intervention groups

Neuromuscular electrical stimulation protocol with the aim of creating muscle contraction consist of 40-minute sessions, 3 day per week for 8 weeks

Main outcome variables

serum glucose level

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20100523003998N1**

Registration date: **2020-10-25, 1399/08/04**

Registration timing: **prospective**

Last update: **2021-01-27, 1399/11/08**

Update count: **1**

Registration date

2020-10-25, 1399/08/04

Registrant information

Name

ghadamali talebi

Name of organization / entity

Babol univercity of medical sciences

Country

Iran (Islamic Republic of)

Phone

+98 11 3219 4641

Email address

talebiali2@yahoo.co.in

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-10, 1399/08/20

Expected recruitment end date

2021-05-10, 1400/02/20

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Neuromuscular Electrical Stimulation on serum glucose level condition in Children and Adolescents with Type 1 Diabetes Mellitus

Public title

"Effect of Neuromuscular Electrical Stimulation on Type 1 Diabetes Mellitus"

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Children and adolescents with type 1 diabetes with the age range of 7 to 18 years History of at least one year from the onset of the disease

Exclusion criteria:

History of known neuromuscular diseases History of

convulsions and use of anticonvulsant drugs
Heart disease
Infectious diseases
Sensory disturbance
Intolerance to electrical stimulation
Other contraindications to the use of electrical stimulation
Professional athletes
Incidence of side effects

Age

From **7 years** old to **18 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **35**

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 Babol University of Medical Sciences

Street address

Ganjafrooz street - Univercity square - Babol univercity of medical sciences

City

Babol

Province

Mazandaran

Postal code

47176-47745

Approval date

2020-09-26, 1399/07/05

Ethics committee reference number

IR.MUBABOL.REC.1399.298

Health conditions studied

1

Description of health condition studied

Type 1 diabetes mellitus

ICD-10 code

E10.9

ICD-10 code description

Type 1 diabetes mellitus without complications

Primary outcomes

1

Description

serum glucose level

Timepoint

Before the intervention, 2 and 6 weeks after the last session

Method of measurement

blood sample

Secondary outcomes

1

Description

HbA1c

Timepoint

Before the intervention, 2 and 6 weeks after the last session

Method of measurement

Blood sample

2

Description

The average weekly dose of total daily dose of insulin

Timepoint

daily

Method of measurement

Daily information form

Intervention groups

1

Description

Intervention group: To apply neuromuscular electrical stimulation (NMES) the stimulator device of Novin, Made in Iran, model 710P PLUS will be used with the aim of creating muscle contraction in the form of a balanced two-phase pulsed current with parameters of frequency 35 Hz, duration 300 microsecond, with ratio on to off 1 to 3 with a time of 5 seconds on and 15 seconds off with an intensity that is tolerable in two stages of 20 minutes with an interval of 10 minutes between the two stages to prevent possible fatigue and discomfort of children. In the first stage, 4 electrodes (6cm.4cm) will be placed bilaterally on the Quadriceps muscle bulk on both the left and right sides. In order to activate the maximum muscle fibers, one electrode will be wrapped around the proximal and lateral and the other around the distal and medial part of the thigh. The second stage is similar to the first stage, and this time the electrodes will be placed on the bulk of the right and left Hamstring muscles. The NMES protocol consists of 40-minute sessions, 3 days per week, for 8 weeks.

Category

Recruitment centers

1

Recruitment center

Name of recruitment center

Pediatric Hospital Of Amirkola

Full name of responsible person

Ghadamali Talebi

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Ganjafrooz Street, Babol University Of Medical Sciences

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Reza Ghadimi

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hribabol@gmail.com

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Babol 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

Babol University of Medical Sciences

Full name of responsible person

Fatemeh Fallah

Position

master student

Latest degree

Bachelor

Other areas of specialty/work

Physiotherapy

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Shahid Namjoo street, Shahid Namjoo 9

City

Fereydunkenar

Province

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Email

Saj.flh94@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Babol University of Medical Sciences

Full name of responsible person

Ghadamali Talebi

Position

Associate professor

Latest degree

Ph.D.

Other areas of specialty/work

Physiotherapy

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Person responsible for updating data

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Other areas of specialty/work

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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