Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 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)

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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
Ganjafroz 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

Treatment - Devices

Recruitment centers

1

Recruitment center

Name of recruitment center
Pediatric Hospital Of Amirkola

Full name of responsible person
Ghadamali Talebi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
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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
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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Person responsible for scientific inquiries

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Position
Associate professor

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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