

Clinical Trial Protocol

Iranian Registry of Clinical Trials

21 Jul 2026

Comparison of two methods of carbohydrate counting and fixed-dose insulin in glycemic control in children with type 1 diabetes

Protocol summary

Study aim

Comparison of two methods of carbohydrate counting and fixed-dose insulin in glycemic control in patients with type 1 diabetes

Design

This study is a randomized, clinical trial on 76 patients.

Settings and conduct

The current study is a randomized clinical trial and was conducted on a population of 6 to 18 years old with type 1 diabetes who referred to the diabetes clinic of Children's Medical Center. Patients will be randomly placed in the group under sugar control intervention with fixed-dose insulin method to determine mealtime insulin and will be completely unaware of the randomization process.

Participants/Inclusion and exclusion criteria

The research community includes; Population 6-18 years old with type 1 diabetes referring to the diabetes clinic of the Children's Medical Center, who have been diagnosed for at least six months and are undergoing insulin treatment and basic education in terms of diabetic diet and are not on their honeymoon period. Other underlying diseases, such as liver or kidney failure, history of feeding through a digestive tube, and lack of written consent to enter the study, are considered to exclude patients from the plan.

Intervention groups

Intervention group 1 - Patients are randomly assigned to the group under sugar control intervention with carbohydrate counting method to determine mealtime insulin. Finally, the changes of each of the measured parameters in two groups before and after the intervention will be reviewed Intervention group 2 - Patients are randomly assigned to the group under sugar control intervention with fixed-dose insulin method to determine mealtime insulin.

Main outcome variables

Glucose level, HbA1C level, The total amount of insulin received daily, Triglyceride, Cholesterol, LDL, HDL

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20231016059738N1**

Registration date: **2023-11-05, 1402/08/14**

Registration timing: **prospective**

Last update: **2023-11-05, 1402/08/14**

Update count: **0**

Registration date

2023-11-05, 1402/08/14

Registrant information

Name

shadi niliyeh

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 6693 0024

Email address

shadi.niliyeh65@googlemail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-11-21, 1402/08/30

Expected recruitment end date

2024-03-19, 1402/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of two methods of carbohydrate counting and fixed-dose insulin in glycemic control in children with type 1 diabetes	
Public title	Glycemic control in children with type 1 diabetes
Purpose	Treatment
Inclusion/Exclusion criteria	
Inclusion criteria:	Type 1 diabetes patients 6 to 18 years old, who have been diagnosed for at least six months Treated with insulin They are not in the honeymoon period Have been subjected to basic training in terms of diabetic diet
Exclusion criteria:	Underlying diseases such as liver or kidney failure A history of feeding through a digestive tube Failure to provide written consent to enter the study
Age	From 6 years old to 18 years old
Gender	Both
Phase	2
Groups that have been masked	No information
Sample size	Target sample size: 76
Randomization (investigator's opinion)	Randomized
Randomization description	They will be allocated to two intervention groups A and B using the block randomization method and using the https://www.sealedenvelope.com/ system with blocks of 4 and with a ratio of 1:1.
Blinding (investigator's opinion)	Not blinded
Blinding description	
Placebo	Not used
Assignment	Parallel
Other design features	
Secondary Ids	empty
Ethics committees	
<u>1</u>	
Ethics committee	
Name of ethics committee	Research Ethics Committees of children's Medical Center Tehran University of Medical Sciences
Street address	Central building of Tehran University of Medical Sciences, Qods Street Intersection, Keshavarz Blvd., Tehran
City	Tehran
Province	Tehran
Postal code	1417653761
Approval date	2023-09-23, 1402/07/01
Ethics committee reference number	IR.TUMS.CHMC.REC.1402.112
Health conditions studied	
<u>1</u>	
Description of health condition studied	Type 1 diabetes
ICD-10 code	E10.9
ICD-10 code description	Type 1 diabetes mellitus without complications
Primary outcomes	
<u>1</u>	
Description	Glucose level
Timepoint	At the beginning of the study and after the intervention
Method of measurement	Paraclinic – Laboratory
<u>2</u>	
Description	HbA1c
Timepoint	At the beginning of the study and after the intervention
Method of measurement	Paraclinic – Laboratory
<u>3</u>	
Description	The Total Amount Of Insulin Received Daily
Timepoint	At the beginning of the study and after the intervention
Method of measurement	Questionnaire-Clinical File
<u>4</u>	
Description	Cholesterol
Timepoint	At the beginning of the study and after the intervention
Method of measurement	Paraclinic – Laboratory
<u>5</u>	
Description	Triglyceride

Timepoint

At the beginning of the study and after the intervention

Method of measurement

Paraclinic - Laboratory

6**Description**

HDL

Timepoint

At the beginning of the study and after the intervention

Method of measurement

Paraclinic - Laboratory

7**Description**

LDL

Timepoint

At the beginning of the study and after the intervention

Method of measurement

Paraclinic - Laboratory

Secondary outcomes

empty

Intervention groups**1****Description**

Intervention group: Patients are randomly assigned to the group under sugar control intervention with carbohydrate counting method to determine mealtime insulin. Finally, the changes of each of the measured parameters in two groups before and after the intervention will be reviewed

Category

Treatment - Drugs

2**Description**

Intervention group: Patients are randomly assigned to the group under sugar control intervention with fixed-dose insulin method to determine mealtime insulin. Finally, the changes of each of the measured parameters in two groups before and after the intervention will be reviewed

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Children's Medical Center Diabetes Clinic

Full name of responsible person

Fateme Siari Fard

Street address

Children's Medical Center, No. 62, next to Imam Khomeini Hospital, Dr. Mohammad Gharib St., at the end of Keshavarz Blvd., Tehran

City

Tehran

Province

Tehran

Postal code

1419733151

Phone

+98 21 6147 9000

Email

cmcpr@tums.ac.ir

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Nima Rezaei

Street address

Building No. 1, Faculty of Medicine, Porsina St. , Quds St. Enghelab St.,Tehran

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1461884513

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deanmed@tums.ac.ir

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

Yes

Title of funding source

Tehran University of Medical Sciences

Proportion provided by this source

1

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**

Tehran University of Medical Sciences

Full name of responsible person

Shadi Niliyeh

Position

Subspecialty Assistant

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

Street address

Children's Medical Center, No. 62, next to Imam Khomeini Hospital, Dr. Mohammad Gharib St., at the end of Keshavarz Blvd., Tehran

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shadi.niliyeh65@googlemail.com

Person responsible for scientific inquiries**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Fateme Siari Fard

Position

Associate professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

Street address

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Person responsible for updating data**Contact****Name of organization / entity**

Tehran University of Medical Sciences

Full name of responsible person

Shadi Niliyeh

Position

Subspecialty Assistant

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

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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

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Data can potentially be shared after de-identifying individuals

When the data will become available and for how long

The access period starts 6 months after the results are published

To whom data/document is available

The data will be available to researchers working in academic and scientific institutions and people working in industry

Under which criteria data/document could be used

Unlimited

From where data/document is obtainable

Shadi Niliyeh . 09131841595 .
shadi.niliyeh65@googlemail.com

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

Unlimited

Comments