Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Investigating the effect of metformin on vascular function and cardiovascular risk factors in children and adolescents with type 1 diabetes: a randomized, double-blind clinical trial

Protocol summary

Study aim
Determining the effect of metformin on endothelial function and cardiovascular disease risk factors in children and adolescents with type 1 diabetes.

Design
A double-blind parallel clinical trial by block allocation on 52 children and adolescents with type 1 diabetes

Settings and conduct
This study is a double-blind clinical trial in children and adolescents with type 1 diabetes for 6 months. Patients who refer to Mofid Children's Hospital will be invited to participate in the study. The participants will be randomly divided into 2 groups (placebo group, group receiving metformin) and they will be asked to consume 500 mg of supplement or placebo daily. The participants and the researcher will not be aware of the type of drug or placebo received.

Participants/Inclusion and exclusion criteria
Inclusion criteria: • Age 8 to 21 years • Body mass index (BMI) percentile for ages 5 to 85 • Receiving insulin (Recombinant, NPH, Regular) • Not using metformin in the past year • Diagnosis of type 1 diabetes (at least 5 years) • Not suffering from diabetic ketoacidosis or hypoglycemia (blood sugar level less than 50 mg/dL) in the last 6 months • Not using metformin in the past year • Not taking anti-hypertensive, anti-inflammatory, anti-coagulant, fat-reducing, weight-reducing and antioxidant drugs in the last 6 months • Willingness to participate in the plan Non-inclusion criteria: • Pregnant or lactating people • Having severe side effects of metformin •Suffering from endocrine disorders such as hypothyroidism • Any acute illness that leads to hospitalization of the patient • Lack of compliance (the patient does not want to continue participating in the study for any reason)

Intervention groups
In the intervention and control groups, respectively, Metformin and placebo will be used at a dose of 500 mg twice a day for 6 months.

Main outcome variables
Flow-mediated dilatation

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20230930059564N1**
Registration date: **2023-11-20, 1402/08/29**
Registration timing: **prospective**

Last update: **2023-11-20, 1402/08/29**
Update count: **0**

Registration date
2023-11-20, 1402/08/29

Registrant information

Name
Asieh Mosallanejad

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 912 515 0578

Email address
mosalladr@sbmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2023-12-21, 1402/09/30

Expected recruitment end date
2024-06-18, 1403/03/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigating the effect of metformin on vascular function and cardiovascular risk factors in children and adolescents with type 1 diabetes: a randomized, double-blind clinical trial

Public title

Investigating the effect of metformin on vascular function and cardiovascular risk factors in children and adolescents with type 1 diabetes

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Age 8 to 21 years Body mass index (BMI) percentile for ages 5 to 85 Receiving insulin (Recombinant, NPH, Regular) Not using metformin in the past year Diagnosis of type 1 diabetes (at least 5 years) Not suffering from diabetic ketoacidosis or hypoglycemia (blood sugar level less than 50 mg/dL) in the last 6 months Not using metformin in the past year Not taking anti-hypertensive, anti-inflammatory, anti-coagulant, fat-reducing, weight-reducing and antioxidant drugs in the last 6 months Willingness to participate in the plan

Exclusion criteria:

Pregnant or lactating people Having severe side effects of metformin (lactic acidosis, severe digestive problems) Suffering from endocrine disorders such as hypothyroidism Any acute illness that leads to hospitalization of the patient Lack of compliance (the patient does not want to continue participating in the study for any reason)

Age

From **8 years** old to **21 years** old

Gender

Both

Phase

4

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **52**

Randomization (investigator's opinion)

Randomized

Randomization description

Randomization will be done by block allocation. The method of randomization will be such that 13 blocks of four will be considered using the software to equalize the distribution of people in two groups, and then random allocation of people in each block will be done to intervention and control groups.

Blinding (investigator's opinion)

Double blinded

Blinding description

This study will be double-blindness, so that researchers and all participants are unaware of intervention and control groups.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethic Committee of Shahid beheshti University of Medical Sciences

Street address

Arabi Ave, Daneshjoo Blvd, Velenjak

City

Tehran

Province

Tehran

Postal code

1939546311

Approval date

2023-09-22, 1402/06/31

Ethics committee reference number

IR.SBMU.MSP. REC.1402.401

Health conditions studied

1

Description of health condition studied

Type 1 diabetes

ICD-10 code

E10

ICD-10 code description

Type 1 diabetes mellitus

Primary outcomes

1

Description

Flow-mediated dilatation

Timepoint

At the beginning of the study and at the end of 6 month

Method of measurement

Sonography

2

Description

Glycated hemoglobin A1C

Timepoint

At the beginning of the study and at the end of 6 month

Method of measurement
Elisa kit

3

Description
Triglyceride
Timepoint
At the beginning of the study and at the end of 6 month
Method of measurement
Elisa kit

4

Description
Fasting blood sauger
Timepoint
At the beginning of the study and at the end of 6 month
Method of measurement
Elisa kit

5

Description
Body mass index
Timepoint
At the beginning of the study and at the end of 6 month
Method of measurement
Calculate weight divided by height (cm) to the power of two

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: receiving 500 mg metformin twice a day for 6 months
Category
Treatment - Drugs

2

Description
Control group: receiving 500 mg placebo twice a day for 6 months
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Mofid Children's Hospital
Full name of responsible person
Asieh Mosallanejad
Street address
No. 1057, Mofid Children's Hospital, above Hosseinieh Ershad, Shariati St., Tehran, Iran.
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Afshin Zarghi
Street address
Arabi Ave, Daneshjoo Blvd, Velenjak
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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
Shahid Beheshti University of Medical Sciences
Proportion provided by this source
20
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
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Asieh Mosalanejad
Position
University faculty

Latest degree
Subspecialist
Other areas of specialty/work
Assistant Professor of Pediatric Endocrinology & Metabolism
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Person responsible for scientific inquiries

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Person responsible for updating data

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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
Information on the main implications can be shared at the end of the study.
When the data will become available and for how long
The access period will be 6 months after the results are published.
To whom data/document is available
The data from this study will be available only to researchers working in academic and scientific institutions.
Under which criteria data/document could be used
6 months after the publication of the articles obtained from the data of this project, at the request of the person in charge of the project and his consent, the study data can be made available to researchers.
From where data/document is obtainable
Applicants can contact the responsible author via the following email to obtain the required data.
mosalladr@sbmu.ac.ir
What processes are involved for a request to access data/document
Applicants will be able to access the study data by sending an email to the responsible author within a maximum of one week.
Comments