

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@sbm.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.

City

Tehran

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Tehran

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1546815514

Phone

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Email

mosalladr@sbmu.ac.ir

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**Contact****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Asieh Mosallanejad

Position

Assistant Professor of Pediatric Endocrinology & Metabolism

Latest degree

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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Asieh Mosallanejad

Position

Assistant Professor of Pediatric Endocrinology & Metabolism

Latest degree**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 obtainableApplicants can contact the responsible author via the following email to obtain the required data.
mosalladr@sbm.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