

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

30 May 2026

### The Effect of Metformin Accompanied by Insulin on weight and insulin dosage in diabetic type 1 adolescents

#### Protocol summary

##### Study aim

Effects of metformin companionship on insulin dosage and HbA1c in adolescents

##### Design

Two arm parallel group randomized computer-based after they met inclusion criteria. First arm will get "metformin" added to their daily diet; second arm will continue their daily routine regimen with Insulin injection.

##### Settings and conduct

Fifty adolescents between 10 and 20 years old which referred to Mofid childrens hospital, Tehran, Iran with diabetes type 1 will divide into equal groups. At the beginning of study and then every 3 months, HbA1c and Insulin dosage will measure in each groups. Study is double blind; patients and physicians do not notice exact medications, but only researcher examine drug consumption and blood glucose routinely.

##### Participants/Inclusion and exclusion criteria

Diabetic type 1; adolescents between 10 and 20 years old; under multiple daily insulin injections for at least 1 years, without any underlying diseases except diabetes type 1.

##### Intervention groups

Patients will take 500 mg of metformin every 12 hours.

##### Main outcome variables

HbA1c changes and insulin injection dosage in each groups

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20201207049638N1**

Registration date: **2020-12-19, 1399/09/29**

Registration timing: **retrospective**

Last update: **2020-12-19, 1399/09/29**

Update count: **0**

##### Registration date

2020-12-19, 1399/09/29

##### Registrant information

###### Name

Hedyeh Saneifard

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 2620 1399

###### Email address

h.saneifard@sbm.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2020-01-30, 1398/11/10

##### Expected recruitment end date

2020-03-05, 1398/12/15

##### Actual recruitment start date

2020-01-30, 1398/11/10

##### Actual recruitment end date

2020-03-05, 1398/12/15

##### Trial completion date

2020-12-05, 1399/09/15

##### Scientific title

The Effect of Metformin Accompanied by Insulin on weight and insulin dosage in diabetic type 1 adolescents

##### Public title

Effect of Metformin in control of Diabetes type 1

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

###### Inclusion criteria:

Age from 10 to 20 years old Duration of Type 1DM more

than one year Insulin dosage more than one unit/ kg /day  
Multiple daily insulin injections from at least 1 year ago  
HbA1c more than 8% in the past 6 months

**Exclusion criteria:**

Nephropathy Proliferative retinopathy Diabetic ketoacidosis more than twice a year Recurrent severe hypoglycemia Current insulin therapy by conventional method (NPH plus Reg) Renal or hepatic dysfunction

**Age**

From **10 years** old to **20 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

- Participant
- Care provider

**Sample size**

Target sample size: **50**

Actual sample size reached: **50**

**Randomization (investigator's opinion)**

Randomized

**Randomization description**

Randomization made by an application "Randomizer" and was totally computer-based. Patients divided into two groups randomly and equally.

**Blinding (investigator's opinion)**

Double blinded

**Blinding description**

Patients and physician was not notified about prescribed drug (metformin) and only researcher was notified about studied groups.

**Placebo**

Not used

**Assignment**

Parallel

**Other design features**

**Secondary Ids**

empty

**Ethics committees**

**1**

**Ethics committee**

**Name of ethics committee**

Ethics Committee, School of Medicine, Shahid Beheshti University of Medical Sciences

**Street address**

Shahid Beheshti Medical School, Daneshjoo Blvd., Yaman Ave., Chamran Highway

**City**

Tehran

**Province**

Tehran

**Postal code**

1967853916

**Approval date**

2020-01-14, 1398/10/24

**Ethics committee reference number**

IR.SBMU.MSP.REC.1398.869

**Health conditions studied**

**1**

**Description of health condition studied**

Diabetes Mellitus Type 1

**ICD-10 code**

E10.9

**ICD-10 code description**

Type 1 diabetes mellitus without complications

**Primary outcomes**

**1**

**Description**

HbA1C concentration alteration after metformin consumption

**Timepoint**

Before intervention, 3 months, 6 months, and 9 months after intervention

**Method of measurement**

Blood test

**2**

**Description**

Creatinine concentration alteration after metformin consumption

**Timepoint**

Before intervention, 3 months, 6 months, and 9 months after intervention

**Method of measurement**

Blood test

**Secondary outcomes**

empty

**Intervention groups**

**1**

**Description**

Control group: patients who were under multiple daily insulin injection. dosage is based on patients weight. Basal insulin: Lantus insulin by Sanofi 100U/ml, Bolus Insulin: Novorapid insulin by Novorapid 100U/ml

**Category**

Treatment - Drugs

**2**

**Description**

Intervention group: patients who were under multiple daily insulin injection like control group, 500 mg metformin, every 12 hours, added to their medication for 9 months. Metformin tablets by Abidi company.

**Category**

Treatment - Drugs

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

Mofid children's hospital

**Full name of responsible person**

Hedyeh Saneifard

**Street address**

Mofid Children's hospital, Shariati Ave., Tehran, Iran

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info-mch@sbmu.ac.ir

**Web page address**<http://mch.sbmu.ac.ir/index.jsp?fkeyid=&siteid=113&pageid=237>**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Seyed Ali Ziai

**Street address**

Dept. Pharmacology, School of Medicine, Shahid Beheshti University of Medical Sciences, Koodakyar St. Daneshjoo Blvd., Evin, Tehran, Iran

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aliziai@sbmu.ac.ir

**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**

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**

Shahid Beheshti University of Medical Sciences

**Full name of responsible person**

Hedyeh Saneifard

**Position**

Assistant Professor

**Latest degree**

Subspecialist

**Other areas of specialty/work**

Pediatrics

**Street address**

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

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**Position**

Assistant Professor

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## Person responsible for updating data

### Contact

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Shahid Beheshti University of Medical Sciences

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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**

All data will presented completely

**When the data will become available and for how long**

After publication

**To whom data/document is available**

All researchers who request data

**Under which criteria data/document could be used**

In case of citation of the study

**From where data/document is obtainable**

Corresponding author

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

Authors have to contact corresponding author via Email and in case of citation in their article, all data will share with them.

**Comments**