

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

29 Jun 2026

### The Effect of metformin as an adjunct therapy in adolescents with Type 1 Diabetes

#### Protocol summary

##### Summary

Objectives: investigation the effect of metformin as an adjunct therapy in adolescents with poorly controlled type 1 diabetes. Design: a quasi-experimental (an uncontrolled before and after) study, sample size 29patients, single center in endocrine clinic in Children's Medical Center, without blinding, without randomization. Intervention: Metformin tablet is added to patient's insulin therapy for 12months. Inclusion criteria: Age >10; Duration of type 1 diabetes (T1DM) >1 year; Insulin dosage>1u/kg/d; HbA1C>8% (relative control). Exclusion criteria: Nephropathies; Retinopathies; Occurrence of diabetic ketoacidosis (DKA) more than twice per year; acute hypoglycemia with loss of consciousness to a level necessitating help more than twice per year; Liver diseases or other underlying diseases. The outcome variables included Hemoglobin A1c protein, Serum creatinine, and lactate and lipid level.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016120110988N5**  
Registration date: **2016-12-06, 1395/09/16**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2016-12-06, 1395/09/16

##### Registrant information

##### Name

Fatemeh Sayarifard

##### Name of organization / entity

Tehran University of Medical Sciences, children medical center

##### Country

Iran (Islamic Republic of)

##### Phone

00982166935848-00982161475

##### Email address

f-sayarifard@tums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

Vice chancellor for research, Tehran University of Medical Sciences

##### Expected recruitment start date

2014-03-11, 1392/12/20

##### Expected recruitment end date

2014-12-11, 1393/09/20

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

The Effect of metformin as an adjunct therapy in adolescents with Type 1 Diabetes

##### Public title

Metformin as an adjunct therapy in type 1 diabetes

##### Purpose

Treatment

##### Inclusion/Exclusion criteria

Inclusion criteria included Age >10; Duration of type 1 diabetes (T1DM) >1 year; Insulin dosage>1u/kg/d; HbA1C>8% (relative control). Exclusion criteria included Nephropathies; Retinopathies; Occurrence of diabetic ketoacidosis (DKA) more than twice per year; Acute hypoglycemia with loss of consciousness to a level necessitating help more than twice per year; Liver diseases or other underlying diseases

##### Age

From **10 years** old to **17 years** old

#### Gender

Both

#### Phase

N/A

#### Groups that have been masked

No information

#### Sample size

Target sample size: **29**

#### 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 Tehran University of Medical Sciences

##### Street address

Tehran University of Medical Sciences

##### City

Tehran

##### Postal code

#### Approval date

2014-03-09, 1392/12/18

#### Ethics committee reference number

IR.TUMS.REC.1395.2894

## Health conditions studied

### 1

#### Description of health condition studied

Diabetes 1

#### ICD-10 code

E10

#### ICD-10 code description

Insulin-dependent diabetes mellitus

## Primary outcomes

### 1

#### Description

HbA1C

#### Timepoint

Before the intervention and repeated with 3 months intervals till the end of study (12 months)

#### Method of measurement

Laboratory

### 2

#### Description

Serum creatinine

#### Timepoint

Before the intervention and at the end of the study (12 months)

#### Method of measurement

Laboratory

### 3

#### Description

Serum lactate

#### Timepoint

Before the intervention and at the end of the study (12 months)

#### Method of measurement

Laboratory

### 4

#### Description

Serum lipids

#### Timepoint

Before the intervention and at the end of the study (12 months)

#### Method of measurement

Laboratory

## Secondary outcomes

empty

## Intervention groups

### 1

#### Description

metformin tablet (MINOO-METFORMIN 500MG TAB) was added to patient's insulin therapy with the following dosages: - weight < 50 kg: starting with 500 mg/day and then increasing gradually to 1000 mg/day - 50 kg<weight<75 kg: starting with 500 mg/day and then increasing gradually to 1500 mg/day - Weight>75kg: starting with 500 mg/day and then increasing gradually to 2000 mg/day The above dosages were prescribed in three equally divided doses along with meals. Metformin was administered for 12 months.

#### Category

Treatment - Drugs

## Recruitment centers

### 1

#### Recruitment center

Name of recruitment center

Children's Medical Center, Tehran University of  
Medical Sciences

**Full name of responsible person**

Abdollah Didban

**Street address**

**City**

Tehran

## Sponsors / Funding sources

### 1

**Sponsor**

**Name of organization / entity**

Vice Chancellor for research of Tehran University of  
Medical Sciences

**Full name of responsible person**

Masud Yunesian

**Street address**

Tehran University of Medical Sciences

**City**

Tehran

**Grant name**

**Grant code / Reference number**

**Is the source of funding the same sponsor  
organization/entity?**

Yes

**Title of funding source**

Vice Chancellor for research of Tehran University of  
Medical Sciences

**Proportion provided by this source**

100

**Public or private sector**

*empty*

**Domestic or foreign origin**

*empty*

**Category of foreign source of funding**

*empty*

**Country of origin**

**Type of organization providing the funding**

*empty*

## Person responsible for general inquiries

**Contact**

**Name of organization / entity**

Tehran University of Medical Sciences

**Full name of responsible person**

Aria Setoodeh

**Position**

Associate Professor

**Other areas of specialty/work**

**Street address**

Children's Medical Center, Tehran University of  
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## Person responsible for scientific inquiries

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## Person responsible for updating data

**Contact**

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Tehran University of Medical Sciences

**Full name of responsible person**

Fatemeh Sayarifard

**Position**

Assistant Professor

**Other areas of specialty/work**

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

*empty*

**Study Protocol**

*empty*

**Statistical Analysis Plan**

*empty*

**Informed Consent Form**

*empty*

**Clinical Study Report**

*empty*

**Analytic Code**

*empty*

**Data Dictionary**

*empty*