Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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 ketoacidocis (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 ketoacidocis (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 Medical Sciences, Tehran, Iran

City

Tehran

Postal code

Phone

+98 21 61475

Fax

Email

setoodeh@tums.ac.ir

Web page address

Person responsible for scientific 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 Medical Sciences, Tehran, Iran.

City

Tehran

Postal code

Phone

+98 21 61475

Fax

Email

setoodeh@tums.ac.ir

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Fatemeh Sayarifard

Position

Assistant Professor

Other areas of specialty/work

Street address

Tehran University of Medical Sciences

City

Tehran

Postal code

Phone

+98 21 61475

Fax

Email

f-sayarifard@tums.ac.ir

Web page address

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