Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
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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

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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
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Beheshti University of Medical Sciences
Full name of responsible person
Seyed Ali Ziai
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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
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
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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