

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 2026

Cardioprotective Effect of Metformin on the level of micro RNAs, mir-222, mir-195, mir-21a, in type 1 diabetes patients

Protocol summary

Study aim

Cardioprotective Effect of Metformin on the level of micro RNAs, mir-222, mir-195, mir-21a, in type 1 diabetes patients

Design

A randomized controlled clinical trial with a group of 28 patients, enrolled between May 2020 and February 2022, and followed for three months

Settings and conduct

Patients who are referred to Loghman Hospital Endocrinology Clinic will be informed if they are eligible for inclusion. Initially, the number of patients is twice the sample size. Blood samples are taken and medication begins; patients are contacted weekly and questions about regular drug use and possible side effects. Patients get free visits every month. In case of complications or exclusion criteria, the patient will be excluded. After 3 months of taking the drug, blood samples are taken again.

Participants/Inclusion and exclusion criteria

Inclusion criteria: age 19 to 45 years; 5 years after onset of diabetes; insulin treatment; patient's blood glucose control for the past three months; HbA1c between 6.5 to 7.5%; no cardiovascular disease; informed consent
Exclusion criteria: pregnancy or pregnancy intent in the near future; renal failure (creatinine greater than or equal to 1.3); history of intraocular injection; history of cardiovascular disease

Intervention groups

In all patients, plasma levels of the three microRNAs miR-222, miR-195, miR-21a will have measured by PCR, then patients will be treated with metformin at a dose of 500 mg daily for a week. It will reach 2 g daily and then for 12 weeks with adjusted insulin dose and blood glucose monitoring daily, metformin treatment with 2 g daily will continue, then plasma microRNA levels will be measured again

Main outcome variables

Change in the level of miR-222 after metformin; change

in the level of miR-21a after metformin; change in the level of miR-195 after metformin

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20200217046520N1**

Registration date: **2020-03-19, 1398/12/29**

Registration timing: **prospective**

Last update: **2020-03-19, 1398/12/29**

Update count: **0**

Registration date

2020-03-19, 1398/12/29

Registrant information

Name

Mina Moghtaderi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 8877 0065

Email address

minamoghtaderi@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-05-09, 1399/02/20

Expected recruitment end date

2021-02-19, 1399/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Cardioprotective Effect of Metformin on the level of micro RNAs, mir-222, mir-195, mir-21a, in type 1 diabetes patients

Public title

Cardioprotective Effect of Metformin on the level of micro RNAs, mir-222, mir-195, mir-21a, in type 1 diabetes patients

Purpose

Prevention

Inclusion/Exclusion criteria**Inclusion criteria:**

age 19 to 45 years insulin-treated for the past three months the patient's blood sugar has been controlled HbA1c ranged from 6/5 to 7/5 lack of cardiovascular disease it's been 5 years since diabetes informed consent

Exclusion criteria:

pregnancy or pregnancy intent in the near future Kidney failure (creatinine equal to or greater than 1/3) history of cardiovascular disease history of intraocular injection Glycated haemoglobin greater than 7/5

Age

From **19 years** old to **45 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **28**

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 Shahid Beheshti University of Medical Sciences

Street address

School of Medicine, Koodakyar St. Danshjoor Blv,

Velenjak, Shahid Chamran Highway, Tehran, Iran

City

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Province

Tehran

Postal code

1985717443

Approval date

2019-04-30, 1398/02/10

Ethics committee reference number

IR.SBMU.MSP.REC.1398.042

Health conditions studied**1****Description of health condition studied**

Type 1 diabetes

ICD-10 code**ICD-10 code description****2****Description of health condition studied**

Cardiovascular disease

ICD-10 code**ICD-10 code description****Primary outcomes****1****Description**

Plasma levels of micro RNA 222 before and after metformin administration

Timepoint

Plasma level of micro RNA 222 at baseline and 12 weeks after metformin administration

Method of measurement

blood test

2**Description**

Plasma levels of micro RNA 195 before and after metformin administration

Timepoint

Plasma level of micro RNA 195 at baseline and 12 weeks after metformin administration

Method of measurement

blood test

3**Description**

Plasma levels of micro RNA 21a before and after metformin administration

Timepoint

Plasma level of micro RNA 21a at baseline and 12 weeks after metformin administration

Method of measurement

blood test

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 28 Patients 19-45 years old with type 1 diabetes referred to Loghman Hospital Endocrine Clinic. Plasma levels of miR-222, miR-195, miR-21a are first measured, then patients will be treated with metformin for 12 weeks, and then the plasma levels of the above microRNAs will be measured again. SPSS software version 24 is used and paired t-test will be used. $P < 0.05$ was considered as the level of statistical significance

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Endocrine Clinic of Loghman Hakim Hospital

Full name of responsible person

Mina Moghtaderi

Street address

Loghman Hakim Hospital, Makhsoos St, South Karegar Ave

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Dr Afshin Zarghi

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School of Medicine, Koodakyar St. Danshjoor Blv, Velenjak, Shahid Chamran Highway, Tehran, Iran

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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

Mina Moghtaderi

Position

Resident

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

No more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

No - There is not a plan to make this available

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

No - There is not a plan to make this available