Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 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 2012, 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. Danshjoo Blv, Velenjak, Shahid Chamran Highway, Tehran, Iran

City
Tehran

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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loghman.hospital@sbmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Dr Afshin Zarghi

Street address
School of Medicine, Koodakyar St. Danshjoo Blv, Velenjak, Shahid Chamran Highway, Tehran, Iran

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Dean.medicalschool@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
Mina Moghtaderi

Position
Resident

Latest degree
Medical doctor

Other areas of specialty/work
Internal Medicine

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Alzahra Dormitory, Niyayesh Pardis, East Niyayesh Highway

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Person responsible for scientific inquiries

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Position
Resident

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Person responsible for updating data

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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