

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Investigation of Metformin effect on the expression of H19, MEG3, MALAT1 and GAS5 long non-coding RNA levels in patients with type 2 diabetes: a clinical trial study

Protocol summary

Study aim

the findings from this study, along with other studies, could help identify the mechanism of another effect on metformin in type 2 diabetes, which may be contributed by altering the expression of non-coding long-term RNAs.

Design

Clinical trial without control group, before and after drug administration

Settings and conduct

Of the 35 newly diagnosed diabetic patients who referred to the Yasuj Diabetes Clinic, they were asked to take one daily dose of metformin at a dose of 1000 or 500 mg (based on their blood glucose levels) for 2 months. Before and after taking the medication Expression of genes and biochemical parameters in individuals is investigated.

Participants/Inclusion and exclusion criteria

Patients entering the study will have the following conditions: 1.Has a fasting blood glucose level of 126 mg / dl Patients excluded from the study will have the following conditions: 1. A group of patients taking metformin or any other blood glucose lowering drugs and any other drug, such as statin, antihypertensive drugs, anti-inflammatory drugs and an ACE inhibitor. 2. A group of patients with cardiovascular disease and inflammatory diseases (such as lupus, rheumatoid arthritis, etc.) 3. A group of patients with a variety of cancers 4. Group 1 diabetic patients 5. A group of people with hyperlipidemia and hypertension

Intervention groups

The intervention group includes 35 newly diagnosed diabetic patients who receive metformin at a specified dose for 2 months and after 2 months the level of non-coding protein RNA in their blood is measured to reduce the effect of metformin on their expression to become clear.

Main outcome variables

fasting blood glucose level RNA expression H19; MALAT1; MEG3; GAS5 Lipid Indices (Triglycerides, Total Cholesterol, HDL-C, LDL-C)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20190303042903N1**

Registration date: **2019-03-17, 1397/12/26**

Registration timing: **retrospective**

Last update: **2019-03-17, 1397/12/26**

Update count: **0**

Registration date

2019-03-17, 1397/12/26

Registrant information

Name

nasrin parvar

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 61 3378 8908

Email address

nasrin.parvar@yums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

1398-01-20, 777/01/-58

Expected recruitment end date

1398-07-20, 781/01/-1338

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of Metformin effect on the expression of H19, MEG3, MALAT1 and GAS5 long non-coding RNA levels in patients with type 2 diabetes: a clinical trial study

Public title

Effect of metformin on the expression of non-coding long-term RNA in diabetic patients.

Purpose

Diagnostic

Inclusion/Exclusion criteria**Inclusion criteria:**

Has a fasting blood glucose level of 126 mg / dl

Exclusion criteria:

consumer metformin or any other hypoglycemic drug and any other drug like statin, antihypertensive, anti-inflammatory drug, and an ACE inhibitor. A group of patients with cardiovascular disease and inflammatory diseases (such as lupus, rheumatoid arthritis, etc.) A group of patients with a variety of cancers A group of type 2 of diabetes Group of people with hyperlipidemia and hypertension

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **35**

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 Yasuj University of Medical Sciences

Street address

Yasuj, Motahari Blvd, Yasouj University of Medical Sciences

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Yasuj

Province

Kohgilouyeh-va-Boyerahmad

Postal code

7591994799

Approval date

2019-03-03, 1397/12/12

Ethics committee reference number

IR.YUMS.REC.1397.149

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

Diabetes mellitus type II in people New case

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes**1****Description**

Fasting blood glucose

Timepoint

At the beginning of the study (before the intervention) and two months after taking metformin

Method of measurement

With an auto-analyzer device

2**Description**

triglyceride

Timepoint

At the beginning of the study (before the intervention) and two months after taking metformin

Method of measurement

With an auto-analyzer device

3**Description**

Total cholesterol

Timepoint

At the beginning of the study (before the intervention) and two months after taking metformin

Method of measurement

With an auto-analyzer device

4**Description**

Cholesterol in low density lipoprotein

Timepoint

At the beginning of the study (before the intervention) and two months after taking metformin

Method of measurement

With an auto-analyzer device

5

Description

Cholesterol in high density lipoprotein

Timepoint

At the beginning of the study (before the intervention) and two months after taking metformin

Method of measurement

With an auto-analyzer device

6

Description

long non-coding RNA H19

Timepoint

At the beginning of the study (before the intervention) and two months after taking metformin

Method of measurement

With Real-Time device

7

Description

long non-coding RNA MALAT1

Timepoint

At the beginning of the study (before the intervention) and two months after taking metformin

Method of measurement

With Real-Time device

8

Description

long non-coding RNA MEG3

Timepoint

At the beginning of the study (before the intervention) and two months after taking metformin

Method of measurement

With Real-Time device

9

Description

long non-coding RNA GAS5

Timepoint

At the beginning of the study (before the intervention) and two months after taking metformin

Method of measurement

With Real-Time device

Secondary outcomes

1

Description

Long-term non-encoding RNA expression H19

Timepoint

Before intervention and 2 months after intervention

Method of measurement

Laboratory analysis

2

Description

Long-term non-encoding RNA expression MALAT1

Timepoint

Before intervention and 2 months after intervention

Method of measurement

Laboratory analysis

3

Description

Long-term non-encoding RNA expression MALAT1

Timepoint

Before intervention and 2 months after intervention

Method of measurement

Laboratory analysis

4

Description

Long-term non-encoding RNA expression GAS5

Timepoint

Before intervention and 2 months after intervention

Method of measurement

Laboratory analysis

5

Description

Glucose

Timepoint

Before intervention and 2 months after intervention

Method of measurement

mg/dl

6

Description

HbA1c

Timepoint

After intervention

Method of measurement

Percentage

7

Description

Triglycerides

Timepoint

Before and after intervention

Method of measurement

mg/dl

8

Description

Waist

Timepoint

Before and after intervention

Method of measurement

centimeter

9

Description

Hip circumference

Timepoint

Before and after intervention

Method of measurement

centimeter

10

Description

BMI

Timepoint

Before and after intervention

Method of measurement

Kg/m²

11

Description

triglyceride

Timepoint

Before and after intervention

Method of measurement

mg/dl

12

Description

LDL

Timepoint

Before and after intervention

Method of measurement

mg/dl

13

Description

HDL

Timepoint

Before and after intervention

Method of measurement

mg/dl

14

Description

Cholesterol

Timepoint

Before and after intervention

Method of measurement

mg/dl

Intervention groups

1

Description

Since the people who are studying the New Case do not need a control group. After entering the study, these

individuals receive a daily dose of metformin at a dosage of 1000 or 500 mg per day (based on their blood glucose levels) for 2 months a day.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Yasouj University of Medical Sciences

Full name of responsible person

ali mirzaei

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

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Full name of responsible person

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oryad.hossein@yums.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Yasouj 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**

Yasouj University of Medical Sciences

Full name of responsible person

Ali mirzaei

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Biochemistry

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Person responsible for scientific inquiries**Contact****Name of organization / entity**

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Full name of responsible person

Ali mirzaei

Position

Assistant Professor

Latest degree

Ph.D.

Other areas of specialty/work

Biochemistry

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Person responsible for updating data**Contact****Name of organization / entity**

Yasouj University of Medical Sciences

Full name of responsible person

nasrin parvar

Position

MSc student

Latest degree

Bachelor

Other areas of specialty/work

Biochemistry

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

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available