Clinical Trial Protocol
Iranian Registry of Clinical Trials

20 Nov 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
City
Yasuj
Province
Kohgilouyeh-va-Boyrahmad
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
Street address
Yasuj, Motahari Blvd, Yasouj University of Medical Sciences
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Email
mirzaee3a2003@yahoo.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yasouj University of Medical Sciences
Full name of responsible person
Hossein Mari Oryad
Street address
Yasuj, Motahari Blvd, Yasouj University of Medical Sciences
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Province
Kohgilouyeh-va-Boyrahmad
Postal code
7591994799
Phone
+98 74 3334 6078
Email
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 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
Street address
Yasuj, Motahari Blvd, Yasouj University of Medical Sciences
City
Yasuj
Province
Kohgilouyeh-va-Boyrahmad
Postal code
7591994799
Phone
+98 74 3333 7230
Email
nasrin.parvar@yums.ac.ir

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