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
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Iran (Islamic Republic of)
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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
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.

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

Purpose
Diagnostic

Randomization (investigator's opinion)
N/A

Sample size
Target sample size: 35

Randomization description
N/A

Blinding (investigator's opinion)
Not blinded

Blinding description
Not used

Assignment
Single

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

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6

**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

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7

**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

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8

**Description**
Long-term non-encoding RNA expression H19

**Timepoint**
Before intervention and 2 months after intervention

**Method of measurement**
Laboratory analysis

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9

**Description**
Long-term non-encoding RNA expression MALAT1

**Timepoint**
Before intervention and 2 months after intervention

**Method of measurement**
Laboratory analysis

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Secondary outcomes

1

**Description**
Long-term non-encoding RNA expression H19

**Timepoint**
Before intervention and 2 months after intervention
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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Email
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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
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
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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