

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jun 2026

Synchronization of metformin with sitagliptin on the expression of miRNA21, 223 in insulin resistant human adipocyte tissue and serum

Protocol summary

Study aim

Synchronization of metformin with sitagliptin on the expression of miRNA21, 223 in insulin resistant human adipocyte tissue and serum

Design

The first phase: selection of two groups of fat persons with insulin resistant (BMI > 35) and non fat (normal BMI) without insulin resistant and take serum and adipose tissue and determination of level of miRNAs expression with RT-PCR method and compare with together. The second phase: selection of fat person to two groups: one for treat with metformin, and other for treat with metformin and sitagliptin for 2-3 months, than take serum and adipose tissue and determination of level of miRNAs synthesis with RT-PCR method and compare with together.

Settings and conduct

Diabetic Research Center

Participants/Inclusion and exclusion criteria

Selection and entrance conditions: Everybody with diagnosis as diabetic for the first time and new case, and if have HOMA index more than 1.5 are case group and less than 1.5 are control group. Between groups was assimilated in age, sex and some variables. Exit condition: Everybody had diabetes, used to diabetic drugs or insulin injection. Person with hormone therapy or endocrine disorders. Person with renal disorders and cancer or malignant tumors and chemotherapy, are exited from survey.

Intervention groups

Persons that were referred to Diabetes Center of Yazd and are diabetic for the first time selected and they were fat (BMI more than 30) and insulin resistant selected for determination of level of miRNA expression in serum and adipose-tissue and compare with person that are not insulin resistant with normal BMI. Than drug interferences is performed and repeat level of miRNA expression in serum and adipose tissue.

Main outcome variables

Age Sex Weight Height BMI Insulin resistant miRNA
Insulin FBS TG Cholesterol MiRNA changes Metformin
Sitagliptin Treatment group

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180408039225N1**

Registration date: **2018-06-02, 1397/03/12**

Registration timing: **registered_while_recruiting**

Last update: **2018-06-02, 1397/03/12**

Update count: **0**

Registration date

2018-06-02, 1397/03/12

Registrant information

Name

Yosof Naghiaee

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3728 0215

Email address

yosofnaghiaee@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-04-04, 1397/01/15

Expected recruitment end date

2018-09-22, 1397/06/31

Actual recruitment start date

empty

Actual recruitment end date

empty
Trial completion date
empty

Scientific title
Synchronization of metformin with sitagliptin on the expression of miRNA21, 223 in insulin resistant human adipocyte tissue and serum

Public title
Synchronization of metformin with sitagliptin on the expression of miRNA21, 223 in insulin resistant human adipocyte tissue and serum

Purpose
Health service research

Inclusion/Exclusion criteria
Inclusion criteria:
Everybody as diabetic for the first time and new case was selected, and if have HOMA index more than 1.5 are case group and less than 1.5 are control group.

Exclusion criteria:
Everybody as diabetic or used to diabetic drugs or insulin and everybody had hormone therapy or with endocrine disorders, persons with renal disorders and cancer or malignant tumors and had chemotherapy are deleted from survey.

Age
No age limit

Gender
Both

Phase
3

Groups that have been masked
No information

Sample size
Target sample size: **30**

Randomization (investigator's opinion)
N/A

Randomization description

Blinding (investigator's opinion)
Not blinded

Blinding description

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Moral in Biomedical Researches

Street address
Bahonar square_Central Organization of Shahid Sadoughi University

City
Yazd
Province
Yazd
Postal code
8916978477

Approval date
2017-05-23, 1396/03/02

Ethics committee reference number
IR.SSU.REC.1396.40

Health conditions studied

1

Description of health condition studied

Insulin resistance

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

MiRNA changes

Timepoint

First -End

Method of measurement

RT_PCR method

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: Fat persons with insulin resistance.

Division to two groups: one for treat with metformin , and other for treat with metformin and sitagliptin for 2-3 months, than take serum and adipose tissue and determination of level of miRNAs expression with RT_PCR method and compare with together.

Category

Diagnosis

2

Description

Control group: Non fat person without insulin resistance without consumption of drug and take serum and adipose tissue and determination of level of miRNAs expression with RT_PCR method.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Research center of diabetes

Full name of responsible person

Naghiaee, Yousof

Street address

Bahonar square_Research center of diabetes

City

Yazd

Province

Yazd

Postal code

8917693571

Phone

+98 35 3728 0215

Email

yosofnaghiaee@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Mehrparvar, Amir Hoshang

Street address

Bahonar square_central organization of shahid
Sadoughi university

City

Yazd

Province

Yazd

Postal code

8916978477

Phone

+98 35 3146 2146

Email

ah.mehrparvar@gmail.com

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Yazd University of Medical Sciences

Proportion provided by this source

40

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

Yazd University of Medical Sciences

Full name of responsible person

Naghiaee, Yousof

Position

Employee

Latest degree

Ph.D.

Other areas of specialty/work

Biochemistry

Street address

Emam hossein square_Emam Reza complex

City

Yazd

Province

Yazd

Postal code

8916188637

Phone

+98 35 3168 2105

Email

yosofnaghiaee@yahoo.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Naghiaee, Yousof

Position

Employee

Latest degree

Ph.D.

Other areas of specialty/work

Biochemistry

Street address

Emam Hosein square_Emam Reza complex

City

Yazd

Province

Yazd

Postal code

8916188637

Phone

+98 35 3168 2105

Email

yosofnaghiaee@yahoo.com

Person responsible for updating data

Contact

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Naghiaee, Yousof

Position

Employee

Latest degree

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Other areas of specialty/work

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Email

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

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable

Title and more details about the data/document

synchronization of metformin with sitagliptin on the expression of miRNA21,223 in insulin resistant human adipocyte tissue and serum

When the data will become available and for how long

there is not time period

To whom data/document is available

everybody

Under which criteria data/document could be used

in diabetes researchs

From where data/document is obtainable

in e-mail address:yosofnaghiaee@yahoo.com

What processes are involved for a request to access data/document

sendig an e-mail to responsible proposal

Comments