Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jun 2026

Combined metformin and sitagliptin effect on expression levels of proteins involved in insulin resistance (IRS-1/PI3K/Akt/mTOR/GLUT4) in adipose tissue of diabetic patients

Protocol summary

Study aim

Combined metformin and sitagliptin effect on expression levels of proteins involved in insulin resistance IRS-1/PI3K/Akt/mTOR/GLUT4 and miRNA21,223 in adipose tissue of diabetic patients

Design

A form of informed consent and a questionnaire form filled in by me for the patient. Then, a blood sample of 10 ml of blood from each patient is taken prior to taking the medications for blood glucose tests and lipid profiles and insulin. After determining glucose and lipid profiles and insulin resistance, the resistance to insulin IR is determined by patients with HOMA-IR, and patients with an IR of 1.8-2 are included in the study. Patients are nonrandomized into two groups of 5, one 5-person group only metformin, and 5 others receive metformin and sitagliptin. Before taking the drug, patients with a surgeon will receive a sample of abdominal fat from each patient to test and determine the proteins of the insulin message transmission pathway by SDS PAGE elec. and Western Blot. After the treatment for three months, again, the same blood sample and abdominal fat samples are obtained from each patient, as before treatment, for the tests previously mentioned.

Settings and conduct

Yazd Diabetes Therapy, Research Center

Participants/Inclusion and exclusion criteria

Type 2 diabetics(New Case) insulin resistance are referred to the Yazd diabetes mellitus center. The maximum of 10 patients and 5 non-diabetic non-insulin-resistace subjects are selected as the control group.

Intervention groups

The first group of 5 patients received metformin alone. The second group is 5 patients receiving metformin and cyagliptin. 5 non-insulin-resistant non-diabetic subjects as control group

Main outcome variables

Combined metformin and sitagliptin effect on expression levels of proteins involved in insulin resistance IRS-1/PI3K/Akt/mTOR/GLUT4

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171018036870N2**
Registration date: **2018-08-26, 1397/06/04**
Registration timing: **retrospective**

Last update: **2019-02-06, 1397/11/17**
Update count: **1**

Registration date

2018-08-26, 1397/06/04

Registrant information

Name

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 35 3820 3417

Email address

didehdar@zbmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-02-04, 1396/11/15

Expected recruitment end date

2018-08-21, 1397/05/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Combined metformin and sitagliptin effect on expression levels of proteins involved in insulin resistance (IRS-1/PI3K/Akt/mTOR/GLUT4) in adipose tissue of diabetic patients

Public title

Combined metformin and sitagliptin effect on expression levels of proteins involved in insulin resistance in adipose tissue of diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Patients with type 2 diabetes who have not yet taken medication and are recently diagnosed with a blood glucose test, the so-called New Case.

Exclusion criteria:

Diabetics who are taking medications, taking pills or taking insulin, have been eliminated.

Age

No age limit

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **15**

Randomization (investigator's opinion)

Not randomized

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

Ethics committee of of Shahid Sadoughi Yazd University of Medical Sciences

Street address

Molecular Biology Dept. - Medical Faculty- Campus of Shahid Sadoughi University of Medical Sciences - Anonymous Martyrs Blvd- Professor Hesabi Blvd- Yazd

City

Yazd

Province

Yazd

Postal code

8915173143

Approval date

2017-07-18, 1396/04/27

Ethics committee reference number

R.SSU.MEDICINE.REC.1396.54

Health conditions studied

1

Description of health condition studied

Type 2 Diabetes Mellitus

ICD-10 code

E11

ICD-10 code description

diabetes (mellitus)(nonobese)(obese): adult-onset maturity-onset nonketotic stable type II non-insulin-dependent diabetes of the young

Primary outcomes

1

Description

Combined metformin and sitagliptin effect on expression levels of proteins involved in insulin resistance IRS-1/PI3K/Akt/mTOR/GLUT4

Timepoint

Measuring the proteins involved in insulin resistance at the beginning of the study (before metformin and citagliptin therapy) and in 90 days (3 months) of drug use (after treatment with metformin and sitagliptin)

Method of measurement

How to measure these proteins using SDS-PAGE and Western blotting

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: We have two intervention groups: Group 1: This group only receive metformin for 3 months. Metformin: Branded metformin hexal, 500 mg (metformin hydrochloride), Made in Germany(Hexal AG), twice daily dosing, morning after breakfast, and evening after dinner.

Category

Diagnosis

2

Description

Intervention group: Group 2: This group receive metformin and sitaglyptin simultaneously for 3 months.Metformin: Branded metformin hexal, 500 mg (metformin hydrochloride), Made in Germany(Hexal AG), twice daily dosing, morning after breakfast, and evening after dinner. Sitaglyptin: Branded Januvia, 50mg manufactured by England, licensed to Merck, twice a day, in the morning after breakfast and at night after dinner.

Category

Diagnosis

3

Description

Control group: 5 non-immune non-insulin-dependent non-insulin-dependent individuals. These people do not use any drugs.

Category

Diagnosis

Recruitment centers

1

Recruitment center

Name of recruitment center

Yazd Diabetes Therapy, Research Center

Full name of responsible person

Mr. Dr. Massoud Rahmanian

Street address

Diabetes Therapy, Research Center- Alley of Art Hall- Beginning of Bahonar Sq. to Azadi Sq.- Shahid Sadoughi Blvd- Yazd

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Rahmanian@ssu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Yazd University of Medical Sciences

Full name of responsible person

Dr. AmirHoushang Mehrparvar

Street address

Third Floor- Shahid Sadoughi University of Medical Sciences and Health Services Yazd- Bahonar Sq. -Yazd

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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

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

Yazd University of Medical Sciences

Full name of responsible person

Reza Didehdar

Position

Ph.D. student of clinical biochemistry

Latest degree

Master

Other areas of specialty/work

Biochemistry

Street address

Yazd-Boulevard, PrMolecular Biology and Biochemistry Dpt.- Medical Faculty- Medical Sciences Pardis- Anonymous Martyrs Bivd- Professor Hassabi- Blvd- Yazd

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Person responsible for scientific inquiries

Contact

Name of organization / entity

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Full name of responsible person

Reza Didehdar

Position

Clinical Biochemistry PhD student

Latest degree
Master

Other areas of specialty/work
Biochemistry

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Person responsible for updating data

Contact

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Other areas of specialty/work
Biochemistry

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City
Yazd

Province
Yazd

Postal code
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didehdar@zbmu.ac.ir

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
Yes - There is a plan to make this available

Informed Consent Form
Yes - There is a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Yes - There is a plan to make this available

Data Dictionary
Yes - There is a plan to make this available

Title and more details about the data/document
If individual data is available to participants without a first and last name, access to them is possible

When the data will become available and for how long
forever

To whom data/document is available
All medical field researchers

Under which criteria data/document could be used
Only for observation is allowed.

From where data/document is obtainable
Visit Iranian Randomized Clinical Trial

What processes are involved for a request to access data/document
Users should certainly mention the name of the Iranian Randomized Clinical Trials as a source.

Comments