

# 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-resistance 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@zsbmu.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 sitagliptin 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. Sitagliptin: 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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**Province**

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**Postal code**

8917693586

**Phone**

+98 35 3728 0226

**Email**

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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**Phone**

+98 35 3724 0171

**Email**

ah.mehrpavar@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 Blvd- Professor Hassabi- Blvd- Yazd

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**Person responsible for scientific inquiries**

**Contact**

**Name of organization / entity**

Yazd University of Medical Sciences

**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**

**Name of organization / entity**

Yazd University of Medical Sciences

**Full name of responsible person**

Reza Didehdar

**Position**

29/5000 Clinical Biochemistry PhD student

**Latest degree**

Master

**Other areas of specialty/work**

Biochemistry

**Street address**

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Anonymous Martyrs Blvd- Professor Hassabi Blvd-  
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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**

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**