Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

The effect of DPP4 inhibitor administration in type 2 diabetes patients under insulin therapy regarding the weight and blood glucose control

Protocol summary

Study aim
Investigation of the effects of adding DPP4 inhibitor in patients with type 2 diabetes treated with insulin in terms of weight changes and glycemic control

Design
The clinical trial was conducted in two intervention groups and one control group, parallel, randomized, blinded groups

Settings and conduct
After recording all of the patients' demographic information including name, age, sex, BMI and etc. patients were divided into 2 groups (Matched for age and BMI) of 30, including the first group receiving 100 mg daily sitaglibtin (DPP4 inhibitor) (Construction pharmaceutical company Abidi) with insulin therapy, the second group received palcebo daily with insulin therapy (as the control group) and will be treated with these drugs for three months. After this time, venous blood sampling will be performed according to fasting conditions and the parameters of lipid profiles (including triglycerides, cholesterol and HDL), FBS, HbA1C, 2hpp and BMI will be evaluated between the studied groups.

Participants/Inclusion and exclusion criteria
Inclusion Criteria: Patients older than 18 years, Type 2 diabetic patients treated with insulin therapy (insulin therapy over the past 6 months.), HbA1C>=7; Exclusion Criteria: Heart problems (Ischemic heart disease, congenital adrenal hyperplasia and valvular diseases), Liver diseases, Renal failure and Pregnancy and lactation.

Intervention groups
The intervention group will include the first group receiving 100 mg of sitagliptin (DPP4 inhibitor) daily with insulin therapy, the second group receiving palcebo daily with insulin therapy, (as the control group) for three months.

Main outcome variables
FBS, 2hpp, HbA1C, lipid profiles (Cholesterol, Tg, HDL), BMI

General information

Reason for update
Acronym
IRCT registration information
IRCT registration number: **IRCT20191231045959N2**
Registration date: **2020-04-24, 1399/02/05**
Registration timing: **retrospective**

Last update: **2020-04-24, 1399/02/05**
Update count: **0**

Registration date
2020-04-24, 1399/02/05

Registrant information
Name
vahideh Sadra
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
2019-06-22, 1398/04/01
Expected recruitment end date
2019-09-23, 1398/07/01
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title

The effect of DPP4 inhibitor administration in type 2 diabetes patients under insulin therapy regarding the weight and blood glucose control

Public title
The effect of sitaglibtin (DPP4 inhibitor) administration in type 2 diabetes patients under insulin therapy regarding the weight, Lipid profile changes and blood glucose control
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients older than 18 years Type 2 diabetic patients treated with insulin therapy (insulin therapy over the past 6 months.) HbA1C>=7
Exclusion criteria:
Heart disease (Ischemic heart disease, Congenital adrenal hyperplasia and valvular disease) Pregnancy and lactation liver Diseases Renal failure Diseases
Age
From **18 years** old
Gender
Both

Phase
2-3
Groups that have been masked

- Participant

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Balanced block randomization
Blinding (investigator's opinion)
Single blinded
Blinding description
The clinical trial is planned in such a way that the study participant does not notice that the doctor is taking the medicine or placebo.
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Tabriz University of Medical Sciences
Street address
Ethics Committee,Tabriz University of Medical Sciences, Golgasht Street , Tabriz
City
Tabriz
Province
East Azarbaijan
Postal code
5166614756
Approval date
2019-06-17, 1398/03/27
Ethics committee reference number
IR.TBZMED.REC.1398.332

Health conditions studied

1

Description of health condition studied
Type 2 diabetes
ICD-10 code
E11
ICD-10 code description
Type 2 diabetes mellitus

Primary outcomes

1

Description
Body Mass Index
Timepoint
Baseline and 3 months after the treatment
Method of measurement
Weigh

2

Description
Fast blood sugar
Timepoint
Baseline and 3 months after the treatment
Method of measurement
Blood Test

3

Description
Triglyceride
Timepoint
Baseline and 3 months after the treatment
Method of measurement
Blood Test

4

Description
Cholestrol
Timepoint
Baseline and 3 months after the treatment
Method of measurement
Blood Test

5

Description
High-Density Lipoprotein
Timepoint
Baseline and 3 months after the treatment
Method of measurement
Blood Test

6

Description
2hpp
Timepoint
Baseline and 3 months after the treatment
Method of measurement
Blood Test

7

Description
HbA1C
Timepoint
Baseline and 3 months after the treatment
Method of measurement
Blood Test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: The first group received 100 mg of sitagliptin (DPP4 inhubitor) (Construction pharmaceutical company Abidi) daily with insulin therapy for 3 months.
Category
Treatment - Drugs

2

Description
Control group: individuals will receive the placebo drug daily with insulin therapy for 3 months.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Tabriz Imam Reza Hospital
Full name of responsible person
Dr. Vahideh Sadra
Street address
Department of Endocrinology, Imam Reza Hospital, Daneshgah Square, Tabriz, East Azarbaijan
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vahideh.sadra@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Tabriz University of Medical Sciences
Full name of responsible person
Dr. MOhammad samei
Street address
Vice chancellor for Research,Tabriz University of Medical Sciences, Golgasht Street, Tabriz
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Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Tabriz 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
Tabriz University of Medical Sciences
Full name of responsible person
Dr. Vahideh Sadra
Position
Assistant Professor
Latest degree
Subspecialist

Other areas of specialty/work
Endocrinology and Metabolism
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Person responsible for scientific inquiries

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Person responsible for updating data

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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
No - There is not 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
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
The total potential data can be shared after unidentifiable people.
When the data will become available and for how long
The access period Starts 3 months after printing the results
To whom data/document is available
All doctors and scientific researchers
Under which criteria data/document could be used
For further studies
From where data/document is obtainable
Dr. Vahideh Sadra, Tel: 00989144146805, Email: vahideh.sadra@gmail.com
What processes are involved for a request to access data/document
Request via email
Comments