Clinical Trial Protocol
Iranian Registry of Clinical Trials

09 Jul 2026

Efficiency of linagliptin on insulin dosage in type 2 diabetes patients with sever renal failure (randomized clinical trial)

Protocol summary

Study aim
Determination of the efficacy of linagliptin on insulin dose in type 2 diabetic patients with severe renal insufficiency

Design
A clinical trial without a control group, with parallel groups, without blinding, was randomized and 96 patients with a size of 4 blocks would be randomly assigned to two groups.

Settings and conduct
The study population was patients aged 18-80 years referred to the Babol Spiritual Educational and Medical Center. Patients are randomly divided into two groups using a random number table by computer. Intervention group1: Treatment with a long-acting insulin regimen (based on the patient's body weight / weight and sugar) will be given subcutaneously. Intervention group2: Treatment with long-acting insulin regimen (based on kg / body weight and patient sugar) will be used subcutaneously plus 5 mg of linaglyptin tablets (Abu Reihan Company) once a day.

Participants/Inclusion and exclusion criteria
Inclusion criteria:Type 2 diabetes, Severe renal failure (GFR below 30), Age 80 - 18 years, HbA1C between 7 and 10 Exclusion criteria:Inability to follow the patient, Discontinue insulin or linagliptin

Intervention groups
Intervention group1: Treatment with a long-acting insulin regimen (based on the patient's body weight / weight and sugar) will be given subcutaneously. Intervention group2: Treatment with long-acting insulin regimen (based on kg / body weight and patient sugar) will be used subcutaneously plus 5 mg of linaglyptin tablets (Abu Reihan Company) once a day.

Main outcome variables
Decreased HbA1C and insulin dose

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20210609051526N1**
Registration date: **2021-06-14, 1400/03/24**
Registration timing: **prospective**

Last update: **2021-06-14, 1400/03/24**
Update count: **0**

Registration date
2021-06-14, 1400/03/24

Registrant information

Name
Neda Meftah

Name of organization / entity

Country
Iran (Islamic Republic of)

Phone
+98 11 3233 8301

Email address
n.meftah@mubabol.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2021-06-22, 1400/04/01

Expected recruitment end date
2022-06-22, 1401/04/01

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title

Efficiency of linagliptin on insulin dosage in type 2 diabetes patients with sever renal failure (randomized clinical trial)

Public title
Efficiency of linagliptin on insulin dosage in type 2 diabetes patients
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Type 2 diabetes Severe renal failure (GFR below 30) Age 80 - 18 years HbA1C between 7 and 10
Exclusion criteria:
Inability to follow the patient Discontinue insulin or linagliptin
Age
From **18 years** old to **80 years** old
Gender
Both

Phase
3
Groups that have been masked
No information
Sample size
Target sample size: **96**
Randomization (investigator's opinion)
Randomized
Randomization description
Patients will be randomly assigned to two groups of 48 using 4 blocks and a ratio of 1: 1. The free website www.randomization.com will be used to generate the allocation sequence. The resulting sequence will be written on separate sheets and placed in sealed envelopes and will be provided to the lead researcher for study.
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
The Ethics Committee of Babol University of Medical Sciences
Street address
Daneshgah Square, Ganjafrooz Avenue
City
Babol
Province
Mazandaran
Postal code
4717647745
Approval date
2021-05-31, 1400/03/10
Ethics committee reference number
IR.MUBABOL.REC.1400.106

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
Change insulin dose
Timepoint
At the beginning of the study and at the end of weeks 12 and 24
Method of measurement
Fasting blood sugar test, HBA1c test

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group1: Treatment with a long-acting insulin regimen (based on the patient's body weight / weight and sugar) will be given subcutaneously.
Category
Treatment - Drugs

2

Description
Intervention group2:Treatment with long-acting insulin regimen (based on kg / body weight and patient sugar) will be used subcutaneously plus 5 mg of linaglyptin tablets (Abu Reihan Company) once a day.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center

Ayatollah Rouhani Hospital

Full name of responsible person
Neda Meftah

Street address
Ruhani Hospital, Daneshgah Square, Ganjafrooz Avenue

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Email
n.meftah@mubabol.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Babol University of Medical Sciences

Full name of responsible person
Reza Ghadimi

Street address
Vice-chancellor Of Research, Daneshgah Square, Ganjafrooz Avenue

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rezaghadimi@yahoo.com

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?
Yes

Title of funding source
Babol 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
Babol University of Medical Sciences

Full name of responsible person
Neda Meftah

Position
Assistant Professor

Latest degree
Subspecialist

Other areas of specialty/work
Internal Medicine

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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available
Justification/reason for indecision/not sharing IPD
There is still no plan for its publish
Study Protocol
Undecided - It is not yet known if there will be a plan to make this available
Statistical Analysis Plan
No - There is not 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