

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 linagliptin tablets (Abu Reihan Company) once a day.

Participants/Inclusion and exclusion criteria

Inclusion criteria: Type 2 diabetes, Severe renal failure (GFR below 30), Age 18 - 80 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 linagliptin 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
City
Babol
Province
Mazandaran
Postal code
47176-41367
Phone
+98 11 3233 8301
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
City
Babol
Province
Mazandaran
Postal code
47176-41367
Phone
+98 11 3219 7667
Email
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
Street address
Ayatollah Rouhani Hospital, Daneshgah Square, Ganjafrooz Avenue
City
Babol
Province
Mazandaran
Postal code
47176-41367
Phone
+98 11 3233 8301
Email
n.meftah@mubabol.ac.ir

Person responsible for scientific 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
Street address
Ayatollah Rouhani Hospital, Daneshgah Square, Ganjafrooz Avenue
City
Babol
Province
Mazandaran
Postal code
47176-41367
Phone
+98 11 3233 8301
Email
n.meftah@mubabol.ac.ir

Person responsible for updating data

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

Street address

Ayatollah Rouhani Hospital, Daneshgah Square,
Ganjafrooz Avenue

City

Babol

Province

Mazandaran

Postal code

47176-41367

Phone

+98 11 3233 8301

Email

n.meftah@mubabol.ac.ir

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