

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Comparing the effect of basal insulin with modified-release gliclazide on glycemic control in type 2 diabetic patients with HbA1C above 10%

Protocol summary

Study aim

Comparing the effect of basal insulin with modified-release gliclazide on glycemic control in type 2 diabetic patients with HbA1C above 10%

Design

An open-label, randomized- clinical trial study with parallel groups and phases 3 on 90 patients. Randomization will be done based on block randomization using Random allocation software.

Settings and conduct

In this study, 90 type 2 diabetic patients with HbA1C above 10% referred to Urmia Imam Khomeini Hospital will be included. Gliclazide-MR 30 mg twice a day in one group and basal insulin 0.1-0.3 u/kg in the other group will be randomly prescribed for three months.

Participants/Inclusion and exclusion criteria

Inclusion criteria: type 2 diabetic patients; with HbA1C above 10%; age over 30 years old. Exclusion criteria: Patients with kidney and liver failure; cardiovascular diseases; consumption of sulfonylureas; Urine ketone positively while having symptoms of polyuria; diabetic ketoacidosis

Intervention groups

In the intervention group gliclazide-MR 30 mg twice a day and in the control group basal insulin 0.1-0.3 u/kg will be prescribed for three month, in addition to the drugs they receive for glycemic control.

Main outcome variables

Hemoglobin A1C (HbA1C); Fasting blood sugar (FBS), Two-hour blood sugar level (BS2hpp)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20230910059395N1**

Registration date: **2023-11-18, 1402/08/27**

Registration timing: **prospective**

Last update: **2023-11-18, 1402/08/27**

Update count: **0**

Registration date

2023-11-18, 1402/08/27

Registrant information

Name

Ebrahim Mohammadi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 44 3345 7286

Email address

mohammadi.e@umsu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2023-12-22, 1402/10/01

Expected recruitment end date

2024-04-19, 1403/01/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the effect of basal insulin with modified-release gliclazide on glycemic control in type 2 diabetic patients with HbA1C above 10%

Public title

Investigating the effect of Gliclazide-MR on glycaemic control in type 2 diabetic patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Type 2 diabetes patients with HbA1C above 10% Age over 30 years

Exclusion criteria:

Patients with kidney and liver failure Heart failure Stroke Pregnancy Previous receipt of gliclazide and insulin Gastric problems Consumption of sulfonylureas Urine ketone positivity while having symptoms of polyuria Diabetic ketoacidosis

Age

From **30 years** old

Gender

Both

Phase

3

Groups that have been masked

No information

Sample size

Target sample size: **90**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients will be divided into two groups using the block randomization method based on generated numbers by Random allocation software. Thus, in this software, first, the number of groups and the total determined sample size will be entered, and then in the block section, the Block randomization method will be implemented. According to the total sample size (90 patients), 23 blocks of 4 will be used. Then, the computer-generated numbers list will be given to the physician, and the physician will assign patients to groups according to the determined order by the software for entry into one of the groups.

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 Imam Khomeini University hospital- Urmia University of Medical Sciences

Street address

Imam Khomeini hospital, Modarres Blvd, Ershad Ave

City

Urmia

Province

West Azarbaijan

Postal code

57157-89397

Approval date

2023-06-21, 1402/03/31

Ethics committee reference number

IR.UMSU.HIMAM.REC.1402.043

Health conditions studied**1****Description of health condition studied**

Type 2 diabetes

ICD-10 code

E08

ICD-10 code description

Diabetes mellitus due to underlying condition

Primary outcomes**1****Description**

HbA1C

Timepoint

Before the intervention and 3 months after the intervention

Method of measurement

High Performance Liquid Chromatography(HPLC)

2**Description**

Fasting blood sugar (FBS)

Timepoint

Before the intervention and 3 months after the intervention

Method of measurement

High Performance Liquid Chromatography (HPLC)

3**Description**

Two-hour blood sugar (BS 2hpp)

Timepoint

Before the intervention and 3 months after the intervention

Method of measurement

High Performance Liquid Chromatography (HPLC)

Secondary outcomes**1****Description**

Excessive drinking and excessive urination

Timepoint

Before the intervention and 3 months after the intervention

Method of measurement

Interview

2

Description

Weight

Timepoint

Before the intervention and 3 months after the intervention

Method of measurement

Weight scale

Intervention groups

1

Description

Intervention group: For patients, in addition to the drugs they receive for glycemic control, gliclazide-MR 30 mg (produced by Actoverco pharmaceutical company) twice a day will be prescribed for three months.

Category

Treatment - Drugs

2

Description

Control group: For patients, in addition to the drugs they receive for glycemic control, basal insulin 0.1-0.3 u/kg (produced by Pouyesh Daru Company) will be prescribed for three months.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini hospital

Full name of responsible person

Dr. Ebrahim Mohhamadi

Street address

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Oroumia University of Medical Sciences

Full name of responsible person

Dr.Saber Gholizadeh

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Urmia University of Medical Sciences, Resalat Ave, Jahad Blvd, Urmia, Iran.

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gholizadeh.s@umsu.ac.ir

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Oroumia 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

Oroumia University of Medical Sciences

Full name of responsible person

Dr. Ebrahim Mohammadi

Position

Assistant professor

Latest degree

Subspecialist

Other areas of specialty/work

Internal Medicine

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Person responsible for scientific

inquiries

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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 no more information

Study Protocol

No - There is not a plan to make this available

Statistical Analysis Plan

Not applicable

Informed Consent Form

No - There is not a plan to make this available

Clinical Study Report

Not applicable

Analytic Code

Not applicable

Data Dictionary

Not applicable