Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Investigation of the Effectiveness of L-Lysine Supplementation in the Control of Fasting Blood Sugar in Type 2 Diabetic Patients.

Protocol summary

Summary

The present study, was designed to investigate the role of L-Lysine supplementation to prevent the diabetic complications in type 2 diabetic patients. Therefore, 50 type 2 diabetic patients in both sexes, with no diabetic complications, that received glibenclamide (10 mg/day) and metformin (1000 mg/day) was selected and then divided into two equal groups, control and case (#25 in each). The case group was received L-Lysine sachets (3 g/day) in addition to the above mentioned drugs for three months. The fasting blood samples of all patients were prepared at first and after three months of treatment. After that, some parameters including fasting blood sugar, insulin, glycated hemoglobin, and other glycated proteins were determined in the whole blood or serum of both groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014120220184N1**
Registration date: **2017-06-05, 1396/03/15**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-06-05, 1396/03/15

Registrant information

Name

Seyedeh Zahra Bathaie

Name of organization / entity

Tarbiat Modares University

Country

Iran (Islamic Republic of)

Phone

+98 21 8288 4567

Email address

bathai_z@modares.ac.ir

Recruitment status

Recruitment complete

Funding source

Iran National Science Fundation (INSF)

Expected recruitment start date

2011-12-31, 1390/10/10

Expected recruitment end date

2012-12-31, 1391/10/11

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Investigation of the Effectiveness of L-Lysine Supplementation in the Control of Fasting Blood Sugar in Type 2 Diabetic Patients.

Public title

L-Lysine therapy of type 2 diabetic patients

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion Criteria: Glycated hemoglobin (HbA1c) ≥ 7%; normal serum insulin level; no history of ketoacidosis, cancer, hyper- or hypothyroidism, diabetic ulcer, chronic renal failure, liver cirrhosis, feverish diseases and consumption of corticosteroids; with serum creatinine ≥ 2 mg/dl; no symptom of hypoinsulinemia such as ketonuria, weight loss; serum glucose level more than 400 mg/dl. Exclusion Criteria: no response to oral agents; need for insulin therapy; appearance of diabetic ulcer or feverish diseases during treatment.

Age

From **41 years** old to **75 years** old

Gender
Both

Phase
0
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Single blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features
Intervention 1 (control): Glibenclamide (10 mg/day) + metformin (1000 mg/day) for 3 months. Intervention 2 (Case): Intervention 1+ L-Lys (3g/day) for 3 months.

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
The Ethics Committee of the Tehran University of Medical Sciences
Street address
Tehran University of Medical Sciences
City
Tehran
Postal code
Approval date
2009-02-23, 1387/12/05
Ethics committee reference number
DHHS-IRB00001641

Health conditions studied

1

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

Primary outcomes

1

Description
Fasting Blood Sugar
Timepoint
3 Months
Method of measurement
Enzymatic Colorimetric

2

Description
Hemoglobin A1c
Timepoint
3 Months
Method of measurement
HPLC

Secondary outcomes

1

Description
Insulin Resistance
Timepoint
3 months
Method of measurement
ELISA

Intervention groups

1

Description
Intervention (Case): Glibenclamide (10 mg/day) + Metformin (1000 mg/day) + L-Lys (3 g/day) for 3 months
Category
Treatment - Drugs

2

Description
Control: Glibenclamide (10 mg/day) + Metformin (1000 mg/day) for 3 months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Endocrinology and Metabolism Research Center (EMRC) Vali-Asr Hospital
Full name of responsible person
Hossein Mimiranpour
Street address
Tehran University of Medical Sciences
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Iran National Science Foundation (INSF)
Full name of responsible person
Dr. Enayati
Street address
Amir Abad, 5th St
City
Tehran
Grant name
Grant code / Reference number
88000429
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Iran National Science Foundation (INSF)
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Tehran University of Medical Sciences
Full name of responsible person
Hossein Mirmiranpour
Position
MD
Other areas of specialty/work
Street address
Endocrinology and Metabolism Research Center (EMRC), Vali-Asr Hospital
City
Tehran
Postal code
Phone
+98 21 6119 2435
Fax
Email
h_mirmiranpoor@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Tarbiat Modares University (TMU)
Full name of responsible person
S. Zahra Bathaie
Position
Professor, Ph.D.
Other areas of specialty/work
Street address
Jalal Ale Ahmad Highway
City
Tehran
Postal code
Phone
+98 21 8288 4567
Fax
Email
bathai_z@modares.ac.ir
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Endocrinology and Metabolism Research Center (EMRC), Vali-Asr Hospital
Full name of responsible person
Hossein Mirmiranpour
Position
Assistant Professor
Other areas of specialty/work
Street address
City
Postal code
Phone
+98 21 6119 2435
Fax
Email
Web page address

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty
Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty