Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

The comparison glycemic control in two group patient treated with insulin alone and insulin plus sulfunyl urea

Protocol summary

Summary

This is a clinical trial study, including 45 diabetes mellitus patients, having a history of this disease treated with one of the sulfonylureas but without effect. The patients will be divided two groups. One group will be treated with insulin and sulforylurea (insulin will be started with dose of 0/2 U/Kg/day and sulfonylurea with previous dose that patient take it) and other group will be treated with insulin alone (with dose of 0/3 U/kg/day). Then the dosage of insulin will be adjusted on the basis of blood glucose levels, and results of blood glucose levels and dosage of the insulin will be compared in two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201204229536N1**
Registration date: **2012-04-30, 1391/02/11**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-04-30, 1391/02/11

Registrant information

Name

Saeedeh Pourmohammad

Name of organization / entity

Metabolic Diseases Research Center, Qazvin University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 28 1336 0084

Email address

spourmohammad@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Qazvin University of Medical Sciences

Expected recruitment start date

2012-03-21, 1391/01/02

Expected recruitment end date

2012-09-19, 1391/06/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison glycemic control in two group patient treated with insulin alone and insulin plus sulfunyl urea

Public title

The comparison glycemic control in two group patient treated with insulin alone and insulin plus sulfunyl urea

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: history of diabetes mellitus; secondary failure (HbA1C>7.5 FBS>140) and treating with sulfonylurea. Exclusion criteria: sever heart failure; renal failure (cr>2.5); artherial failure; take corticosteroide; Diabetic ketoacidosis; liver failure; hypotension and critical illness.

Age

No age limit

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size
Target sample size: **45**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Qazvin University of Medical Sciences Ethic Committee
Street address
Vice chancellor for research, Qazvin University of Medical Sciences, Shahid Bahonar blvd
City
Qazvin
Postal code
Approval date
2011-04-27, 1390/02/07
Ethics committee reference number
28/20/4416

Health conditions studied

1

Description of health condition studied
Type II Diabetes
ICD-10 code
E11
ICD-10 code description
Type II Diabetes

Primary outcomes

1

Description
Blood glucose
Timepoint
4 times a day
Method of measurement
Glucometer

2

Description
Weight gain
Timepoint
3 months after intervention
Method of measurement
Digital scale

3

Description
Hypoglycemic event
Timepoint
3 months after intervention
Method of measurement
Glucometer

Secondary outcomes

1

Description
Dosage of the insulin
Timepoint
4 times a day
Method of measurement
With insulin syringes

Intervention groups

1

Description
Intervention group 1: Insulin 0.2 u/kg /day and sulfonylurea whit previous dose
Category
Treatment - Drugs

2

Description
Intervention group 2: Insulin 0.3 u/kg /day
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Internal Sector of Booali Hospital
Full name of responsible person
Saeedeh Pourmohammad
Street address
Qazvin Metabolic Disease Research Center, Boo-Ali Hospital, Boo-Ali St., Qazvin, Iran
City
Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Qazvin University of Medical Sciences

Full name of responsible person

Saeed Assefzadeh

Street address

Vice chancellor for research, Qazvin University of Medical Sciences, Shahid Bahonar blvd

City

Qazvin

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Qazvin University of Medical Sciences

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

Metabolic Diseases Research Center, Qazvin University of Medical Sciences

Full name of responsible person

Saeedeh pourmohammad

Position

Assistant of Internal Medicine

Other areas of specialty/work

Street address

Qazvin Metabolic Disease Research Center, Boo-Ali Hospital, Boo-Ali St., Qazvin, Iran

City

Qazvin

Postal code

Phone

+98 28 1336 0084

Fax

Email

spourmohammad@qums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Metabolic Diseases Research Center, Qazvin University of Medical Sciences

Full name of responsible person

Saeedeh Pourmohammad

Position

Assistant of Internal Medicine

Other areas of specialty/work

Street address

Qazvin Metabolic Disease Research Center, Boo-Ali Hospital, Boo-Ali St., Qazvin, Iran

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+98 28 1336 0084

Fax

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Person responsible for updating data

Contact

Name of organization / entity

Metabolic Diseases Research Center, Qazvin University of Medical Sciences

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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