Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Insulin regular versus tab repaglinid in patient with DM type 2 that taking NPH l injection

Protocol summary

Summary

A clinical trial was designed to compare regular insulin with repaglinide tablet to control postprandial glucose in DM type 2 patients who are receiving NPH insulin and evaluate two types of drugs effects on FBS, HbA1c and C-peptide level. Inclusion Criteria: 1) DM type 2 patients, 2) BMI>25 3) Receiving full doses of antihyperglycemic agents (Glibenclimide 10mg/daily, Metformin 1500mg/daily) 4) Uncontrolled patients (HbA1c>7.5, PPG>180mg/dl) Exclusion criteria: 1) Diabetes coma, 2) Recurrent or sever hypoglycemic attacks 3) End stage cardiovascular, liver and renal disease 4) Drug history included rifampin, carbamazepin, erythromycin, nifedipin, warfarin, glucocorticoid Patients will be admitted in the hospital before oral drug changes to insulin. Their FBS, 2hPPG, 4pm BS(by set glucometer device) will be measured at base line. Then NPH insulin therapy will be conducted for all patients and those their glucose are not completely controlled with insulin NPH and require additive regular insulin consciously, with full consent will be divided into 2 groups randomly. First group will receive insulin regular up to optimum glucose level and second group will be treated with repalglinide (0.5mg/bd up to maximum 2mg/bd). Our gold standard will be 80-110 for FBS, 140-180 for 2h PPG and <180 mg/dl for 4PM BS. Patients' fasting BS, HbA1c and C-peptide will be measured at baseline and all these tests will be repeated 12 weeks later.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201109177568N1**
Registration date: **2012-03-12, 1390/12/22**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-03-12, 1390/12/22

Registrant information

Name
Hossein Chiti
Name of organization / entity
Zanjan Metabolic Disaese research center
Country
Iran (Islamic Republic of)
Phone
+98 24 1727 0814
Email address
dr.chiti@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Zanjan University of medical science

Expected recruitment start date

2011-10-11, 1390/07/19

Expected recruitment end date

2012-10-23, 1391/08/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Insulin regular versus tab repaglinid in patient with DM type 2 that taking NPH l injection

Public title

Insulin regular versus tab repaglinid in patient with DM type 2

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: 1) DM type 2 patients, 2) BMI>25 3) Receiving full doses of antihyperglycemic agents (Glibenclimide 10mg/daily, Metformin 1500mg/daily) 4) Uncontrolled patients (HbA1c>7.5, PPG>180mg/dl) Exclusion criteria: 1) Diabetes coma, 2) Recurrent or sever hypoglycemic attacks 3) End stage cardiovascular, liver and renal disease 4) Drug history included rifampin, carbamazepin, erythromycin, nifedipin, warfarin, glucocorticoid

Age
No age limit

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **80**

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
Zanjan University of medical science

Street address
Azadi Bulvar

City
Zanajn

Postal code

Approval date
2011-10-09, 1390/07/17

Ethics committee reference number
A-11312-11

Health conditions studied

1

Description of health condition studied
Diabetes mellitus type 2

ICD-10 code
E73.0

ICD-10 code description
impaired glucose tolerance

Primary outcomes

1

Description
postprandial glucose

Timepoint
Before intervention, 12weeks after intervention

Method of measurement
Glucometer

2

Description
FBS

Timepoint
Before intervention, 12weeks after intervention

Method of measurement
labratory

3

Description
4pm BS

Timepoint
Before intervention, 12weeks after intervention

Method of measurement
Glucometer

Secondary outcomes

1

Description
HbA1C

Timepoint
Before intervention, 12weeks after intervention

Method of measurement
Affinity chromatography Boronate

2

Description
Peptide_c

Timepoint
Before intervention, 12weeks after intervention

Method of measurement
Electero chemy luminecance

Intervention groups

1

Description
Control group: Insulin regular up to achieve optimum level of glucose

Category
Treatment - Drugs

2

Description
Repaglinide tab: 0.5mg/bd up to maximum dose of 2mg/bd
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
vali-e-asr Hospital
Full name of responsible person
Dr Hosein Chiti
Street address
City
Zanjan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Zanjan University of mediacl science
Full name of responsible person
Dr Alireza Biglari
Street address
Azadi Boulvar
City
Zanjan
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Zanjan University of mediacl science
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
Vali-e-asr Hospital, Zanajan University of medical science
Full name of responsible person
Dr mariam hajipour
Position
Internal Resident
Other areas of specialty/work
Street address
Shekh fazlollahe nouri avenue, Vali-e-asr hospital
City
Zanjan
Postal code
Phone
+91 11369772
Fax
Email
hajipour@yahoo.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Metabolic Disaese Resaerch Center, Zanajn University of medical science
Full name of responsible person
Dr Hossein Chiti
Position
assisstant professor
Other areas of specialty/work
Street address
sheikhfazollahe nouri avenu, Vali-e-asr hospital
City
Zanjan
Postal code
Phone
+98 24 1727 0815
Fax
Email
h.chiti@yahoo.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Metabolic Disease Resaech center
Full name of responsible person
Dr Zahran Shajari
Position
GP
Other areas of specialty/work
Street address
Sheikh Fazlollahe nouri Avenue, Vali-e-asr hospital
City
Zanajn
Postal code
Phone
00
Fax
Email
adz.shajari@gmail.com
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