Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Differential effects of metformin and pioglithazone on hs-CRP in patients with type II DM.

Protocol summary

Summary

The goal of this randomized clinical trial is comparison of efficacy of metformin and pioglitazone at reduction in hs_CRP level in the patients with type II DM. In this study, 40 patients with DM that have inclusion and exclusion criteria are randomly assigned to receive Metformin 500mg/bd orally for 3 months or Pioglitazone 30 mg/daily orally for 3 months. hs_CRP level will be compared at the end of this study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201109067482N1**
Registration date: **2011-10-17, 1390/07/25**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-10-17, 1390/07/25

Registrant information

Name
Ramak Ghavam
Name of organization / entity
Bouali Hospital
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Iran (Islamic Republic of)
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Recruitment status

Recruitment complete

Funding source

Deputy of Research Qazvin University of Medical Sciences

Expected recruitment start date

2011-04-30, 1390/02/10

Expected recruitment end date

2011-08-01, 1390/05/10

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Differential effects of metformin and pioglithazone on hs-CRP in patients with type II DM.

Public title

Differential effects of metformin and pioglithazone on hs-CRP in patients with type II DM.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Diabetic patients (type 2) receiving diet or monotherapy by sulphonylurea, HbA1C≥7.5 and FBS≥140 Exclusion criteria: known case of inflammatory disease such as IBD, RA, vascultis, recent infection in one month suffering from malignancy, receiving other drug that decrease CRP level .[COX inhibitor (ASA, Celecoxib), platlete aggregation inhibitor (clopidogrel, abciximab), lipid lowering agents (Statins, Ezetimibe, Fenofibrate, Niacin, B blockers, antioxidants (vit E), ACEIs, ARBs ,CCBs except Amlodipine, Tamoxifen], Soye isoflavon enriched food; consumption of oral estrogen that increase CRP level, hypersensitivity to Metformin or Pioglitazone, Insulin use, Corticosteroid use, Cr >1.4 mg/dl, severe abnormal liver function test, pregnancy

Age

From **21 years** old to **80 years** old

Gender

Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
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 Qazvin University of Medical Sciences
Street address
Boali Hospital, Qazvin, Iran
City
Qazvin
Postal code
3413786165
Approval date
2011-04-27, 1390/02/07
Ethics committee reference number
20/2924/د

Health conditions studied

1

Description of health condition studied
diabetes mellitus II
ICD-10 code
E11
ICD-10 code description
non-insulin-dependent diabetes mellitus

Primary outcomes

1

Description
hsCRP
Timepoint
before study and 3 months after treatment
Method of measurement
Kit for CRP_ Latex Inhanced Immunoturbidimetric Assay A Quantitative Test for C-Reactive Protein Determination by Parsazmun company (unitage: mg/L)

Secondary outcomes

1

Description
HbA1C
Timepoint
before study and 3 months after treatment
Method of measurement
Kit for HbA1C in whole blood with Immunoturbidimetric Assay, a Quantitative Test by Parsazmun Company (unitage: %)

Intervention groups

1

Description
Pioglitazone 30 mg/daily, orally for 3 months
Category
Treatment - Drugs

2

Description
Metformin 500mg/bd orally for 3 months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Qazvin University of Medical Sciences
Full name of responsible person
Dr Ramak Ghavam
Street address
Qazvin Boualisina Hos.
City
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Qazvin University of Medical Sciences
Full name of responsible person
Dr. Ramak Ghavam
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City
Qazvin
Grant name
معاونت پژوهشی دانشگاه علوم پزشکی قزوین

Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
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
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Dr. Ramak Ghavam
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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