

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jul 2026

Differential effects of metformin and pioglitazone 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

Country

Iran (Islamic Republic of)

Phone

+98 28 1336 0084

Email address

rghavam@qums.ac.ir

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 pioglitazone on hs-CRP in patients with type II DM.

Public title

Differential effects of metformin and pioglitazone 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 \geq 7.5 and FBS \geq 140 Exclusion criteria: known case of inflammatory disease such as IBD, RA, vasculitis, recent infection in one month suffering from malignancy, receiving other drug that decrease CRP level .[COX inhibitor (ASA, Celecoxib), platelet 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

20/2924/3

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 Enhanced 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

Qazvin

Sponsors / Funding sources**1****Sponsor****Name of organization / entity**

Qazvin University of Medical Sciences

Full name of responsible person

Dr. Ramak Ghavam

Street address

Qazvin Boualisina Hos.

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

Name of organization / entity
Qazvin University of Medical Sciences

Full name of responsible person
Dr. Ramak Ghavam

Position
Internist MD.

Other areas of specialty/work

Street address
Iran,Qazvin, Boualisina Hos.

City
Qazvin

Postal code
3413786165

Phone
+98 28 1333 3036

Fax
+98 28 1332 6033

Email
rghavam@qums.ac.ir ramak.ghavam@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity
Qazvin University of Medical Sciences

Full name of responsible person
Dr Ramak Ghavam

Position
Internist MD.

Other areas of specialty/work

Street address
Qazvin Boualisina Hos.

City
Qazvin

Postal code
3413786165

Phone
+98 28 1333 3036

Fax
+98 28 1332 6033

Email
rghavam@qums.ac.ir ramak.ghavam@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity
Qazvin University of Medical Sciences

Full name of responsible person
Dr. Ramak Ghavam

Position
Internist MD.

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Street address
Qazvin Boualisina Hos.

City
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Phone
+98 28 1336 0084

Fax
+98 28 1332 6033

Email
rghavam@qums.ac.ir ramak.ghavam@yahoo.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