

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

investigation of the effectiveness of combination of losartan with Rocaltrol on treatment of albuminuria in patient with diabetic nephropathy; a clinical trial.

Protocol summary

Summary

Diabetic nephropathy is the most common renal complication of diabetes. Previous study have reported the efficacy of Rocaltrol with Losartan on better treatment of diabetic nephropathy, although the role of vitamin D in reducing GFR and treatment of albuminuria is not clear. This study aim to evaluate the therapeutic effect of this combination strategy on Diabetic Nephropathy. In a double blind clinical trial phase 4, 132 diabetic nephropathy patients with aged 40 to 70 years old will be enrolled in the study. The exclusion criteria consist of patients with serum creatinine rising, $K > 5.5$ and with serum vitamin D deficiency. Then they investigate regarding lipid profile (HDL, LDL, TG, Cholesterol); Ca, P, HbA1C, Urine Albumin and Creatinine. The patients will be divided randomly into two case and control groups by simple sample method. The case group will received combination therapy with Losartan 25 mg/PO twice per day and Rocaltrol one capsule per day for 3 months and control group received Losartan 25 mg/PO twice per day for 3 months. The patient and the researchers are blind to the study. Afterwards, at the end of the study the ACR and other laboratory study will be repeated and the results of both groups will be compared with each other and statistically analyzed.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2015110624903N1**

Registration date: **2015-11-29, 1394/09/08**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-11-29, 1394/09/08

Registrant information

Name

Mehdi Hadidi

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Arak University of Medical Sciences

Expected recruitment start date

2015-06-22, 1394/04/01

Expected recruitment end date

2016-01-22, 1394/11/02

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

investigation of the effectiveness of combination of losartan with Rocaltrol on treatment of albuminuria in patient with diabetic nephropathy; a clinical trial.

Public title

the effectiveness of Rocaltrol on treatment of albuminuria in pateint with diabetic nephropathy.

Purpose

Treatment

Inclusion/Exclusion criteria
 Inclusion criteria: aged between 40-70 years; diabetes mellitus type 2 that at least 3 months past diagnosis; Albuminuria is (urinary albumin >30 mg/24 hours); Signing Informed consent form; ca <9.5 and p <5.5; Not having an active urine analysis regarding Hematuria, pyuria and urine cast or crystal. Exclusion criteria: K > 5.5 mg per deciliter or creatinine rising more than 30% after administration of Losartan; administration of vitamin D agents; acute infectious disease; acute heart failure; cancer; pregnancy; Urinary protein more than 8 gr/24 hours; vitamin D deficiency.

Age
 From **40 years** old to **70 years** old

Gender
 Both

Phase
 4

Groups that have been masked
No information

Sample size
 Target sample size: **132**

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
 Arak University of Medical Scieince

Street address
 A'lam-Al-Hoda Street, Shahid Shiroodi Street, Arak, Markazi Province, Iran

City
 Arak

Postal code

Approval date
 2014-12-22, 1393/10/01

Ethics committee reference number
 1196

Health conditions studied

1

Description of health condition studied

diabetic nephropathy

ICD-10 code

E11.2

ICD-10 code description

Non-insulin-dependent diabetes mellitus with renal complications

Primary outcomes

1

Description

HbA1C

Timepoint

3 month later

Method of measurement

labratory study

2

Description

Albumin to createnin ratio

Timepoint

3 month later

Method of measurement

labratory study

Secondary outcomes

1

Description

Ca

Timepoint

3 month later

Method of measurement

Labratory Study

2

Description

P

Timepoint

3 month later

Method of measurement

Labratory Study

Intervention groups

1

Description

case group : Patients with diabetic nephropathy without vitamin D deficiency (66 patients) enroll to the study considering inclusion and exclusion criteria and they will be investigate regarding lipid profile (HDL, LDL, TG, Cholesterol); Ca, P, HbA1C, Urine Albumin and Creatinine, also the ACR (Urine Albumin to creatinine ratio) will be calculated. They receive combination

therapy with Losartan 25 mg/PO twice per day and Rocaltrol one capsule daily for 3 months. Afterwards, at the end of the study the laboratory study will be repeated and the results of both groups will be compared with each other and statistically analyzed.

Category

Treatment - Drugs

2**Description**

Control group: Patients with diabetic nephropathy without vitamin D deficiency (66 patients) enroll to the study considering inclusion and exclusion criteria and they will be investigate regarding lipid profile (HDL, LDL, TG, Cholesterol); Ca, P, HbA1C, Urine Albumin and Creatinine, also the ACR (Urine Albumin to creatinine ratio) will be calculated. They receive Losartan 25 mg/PO twice per day for 3 months. Afterwards, at the end of the study the laboratory study will be repeated and the results of both groups will be compared with each other and statistically analyzed.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center****Name of recruitment center**

Amir Al Momenin Hospital

Full name of responsible person

DR Mehdi Hadidi

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

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A'lam-Al-Hoda Street, Shahid Shiroodi Street, Arak,
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Arak

Grant name**Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

Title of funding source

Arak 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**

Arak University of Medical sciences

Full name of responsible person

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Position

Resident

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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