

Clinical Trial Protocol

Iranian Registry of Clinical Trials

15 Jul 2026

Resveratrol's Effects in Diabetic Nephropathy

Protocol summary

Summary

Diabetes mellitus (DM) is one of the most important public health burdens, and its prevalence has rapidly increased worldwide over the past decades. One of the most important complications of DM is nephropathy. Resveratrol (3, 5, 4'-trihydroxystilbene) is a natural polyphenolic compound belongs to the large group of polyphenols found in different plant species. The richest natural source of resveratrol is *Polygonum cuspidatum* — a plant root extract of which have been used in oriental folk medicine. Considerable amounts of resveratrol were also found in skin of red grapes, peanuts, groundnuts, and red vine. Resveratrol is considered to have beneficial effects on glucose tolerance and insulin sensitivity, the cardiovascular system, as it has been found to improve vasodilatation, ischaemic preconditioning, both of which seem to be the result of the activation of the endothelial NO synthase enzyme, and to inhibit both platelet aggregation and vascular smooth muscle cell proliferation. Resveratrol itself is an efficient antioxidant, as evidenced by both in vitro and in vivo studies, and, it has also been shown to improve diabetes-related impairments in animals. We hypothesized that resveratrol may have a favorable effects on control of diabetic nephropathy. The aim of this study is to evaluate the safety and effects of resveratrol in treatment of diabetic nephropathy.

General information

Acronym

ReDNeph

IRCT registration information

IRCT registration number: **IRCT2016100716876N2**

Registration date: **2016-11-25, 1395/09/05**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-11-25, 1395/09/05

Registrant information

Name

Mesbah Shams

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4316

Email address

shams@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor of Research, Shiraz University of Medical Sciences

Expected recruitment start date

2016-04-19, 1395/01/31

Expected recruitment end date

2017-01-19, 1395/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Resveratrol's Effects in Diabetic Nephropathy

Public title

Resveratrol's Effects in Diabetic Nephropathy

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: • Type 2 diabetes mellitus (DM) •
Controlled blood sugar [fasting blood sugar (FBS)
<130mg/dl and glycosylated hemoglobin (A1C)<7% •
Urine albumin >20mg/lit in two separate occasions

during the last 3 months period • Serum creatinin < or = 2mg/dl Exclusion Criteria: • Pregnancy • Lactation • Alcoholism • Liver failure (acute or chronic) • Renal failure: serum creatinin >2mg/dl • Glomerulonephritis • Uncontrolled hypertension • Congestive heart failure • Prostate disease • Malignancy • Bilateral renal artery stenosis • Any systemic disease other than DM • Any infection or rheumatologic disorder • Use of warfarin

Age

From **18 years** old to **70 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

1

Registry name

Resveratrol's Effects in Diabetic Nephropathy (ReDNeph)

Secondary trial Id

ClinicalTrials.gov ID: NCT02704494

Registration date

2016-03-10, 1394/12/20

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee, Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences, Zand St.

City

Shiraz

Postal code

Approval date

2015-08-02, 1394/05/11

Ethics committee reference number

IR.SUMS.REC.1394.81

Health conditions studied

1

Description of health condition studied

diabetes mellitus

ICD-10 code

E11-NO8.3

ICD-10 code description

Non-insulin-dependent diabetes mellitus-diabetic nephropathy

Primary outcomes

1

Description

Urine albumin level

Timepoint

before intervention and 3 months after intervention

Method of measurement

miligram per deciliter with immunoturbidometry method

2

Description

Serum creatinin

Timepoint

before intervention and 3months after intervention

Method of measurement

miligram per deciliter

Secondary outcomes

1

Description

Fasting blood sugar (FBS)

Timepoint

before intervention and 3 months after intervention

Method of measurement

miligram per deciliter with colorimetry method

2

Description

Glycosylated hemoglobin (A1C)

Timepoint

before intervention and 3 months after intervention

Method of measurement

enzymatic method

3

Description

Liver aminotransferases (ALT)

Timepoint

before intervention and 3 months after intervention

Method of measurement

colorimetric method

4

Description

Serum insulin level

Timepoint

before intervention and 3 months after intervention

Method of measurement

IRMA

5

Description

Number of patients with adverse events

Timepoint

3 months after initiation of intervention

Method of measurement

questionnaire

6

Description

serum level of aspartate aminotransferase(AST)

Timepoint

before intervention and 3 months after intervention

Method of measurement

colorimetric method

7

Description

serum levels of gamma glutamyl transpeptidase(GGT)

Timepoint

before intervention and 3 months after intervention

Method of measurement

colorimetric method

8

Description

serum triglyceride

Timepoint

before intervention and 3 months after intervention

Method of measurement

colorimetric method

9

Description

serum cholesterol

Timepoint

before intervention and 3 months after intervention

Method of measurement

colorimetric method

10

Description

serum HDL(high density lipoprotein)

Timepoint

before intervention and 3 months after intervention

Method of measurement

colorimetric method

11

Description

serum LDL(low density lipoprotein)

Timepoint

before intervention and 3 months after intervention

Method of measurement

colorimetric method

12

Description

serum level of alkaline phosphatase

Timepoint

before intervention and 3 months after intervention

Method of measurement

colorimetric method

Intervention groups

1

Description

Intervention group: Resveratrol+ Losartan

Resveratrol:500 mg capsule; 1 capsule daily for 3 months
Losartan:25 mg tablet; 1/2 tablet daily for 3 months

Category

Treatment - Drugs

2

Description

Control group:Placebo+ Losartan
Placebo: Carbo methyl cellulose(CMC) 500 mg capsules; 1 capsule daily for 3 months
Losartan:25mg tablet; 1/2 tablet daily for 3 months

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Mottahari Clinic

Full name of responsible person

Azar Sattarinezhad

Street address

Nemazee Square

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research,shiraz university of medical sciences

Full name of responsible person

S. Basir Hashemi, M.D.

Street address

Shiraz university of medical sciences, Zand avenue,
Seventh floor

City

Shiraz

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, shiraz 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**

Internal Medicine Department, Shiraz University of Medical Sciences

Full name of responsible person

Azar Sattarinezhad

Position

Endocrine fellowship

Other areas of specialty/work**Street address**

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Web page address**Person responsible for scientific inquiries****Contact****Name of organization / entity**

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Full name of responsible person

Mesbah Shams

Position

Associate professor of Internal Medicine and Endocrinology

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Shiraz University of Medical Sciences

Full name of responsible person

Mesbah Shams

Position

Associate professor of Internal Medicine and Endocrinology

Other areas of specialty/work**Street address**

Internal Medicine Department, Nemazee Hospital

City

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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