Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of zinc supplementation on proteinuria and sexual function in patients with Type II Diabetes Mellitus

Protocol summary

Summary

The objective of this study is to investigate the effect of zinc supplementation on proteinuria and sexual function in patient with Type II Diaberes Mellitus. In this randomized placebo controlled cross over trial, 50 male diabetic patients with microalbuminuria are enrolled. Patients will be randomly assigned into two groups (25 in each of two groups) to receive 30 mg elemental zinc or placebo for 3 months. After a four- week washout period, the groups will cross-over and the protocol will be repeated. Fasting plasma glucose (FBS), HbA1C, lipid profiles, random urine for albumin and creatinine (AC Ratio), GFR, and plasma zinc and testosterone levels will be measured before and after each period. Patients' sexual function will be determined with International Index of Erectile Function-5 (IIEF-5).

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138806091179N3**
Registration date: **2011-03-20, 1389/12/29**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2011-03-20, 1389/12/29

Registrant information

Name

Faranak Sharifi

Name of organization / entity

Zanjan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 24 1727 0815

Email address

zmdrc@zums.ac.ir

Recruitment status

Recruitment complete

Funding source

Metabolic Diseases Research Center, Zanjan University of Medical Sciences

Expected recruitment start date

2009-09-23, 1388/07/01

Expected recruitment end date

2010-08-22, 1389/05/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of zinc supplementation on proteinuria and sexual function in patients with Type II Diabetes Mellitus

Public title

Effect of zinc supplementation on proteinuria and sexual function in patients with Type II Diabetes Mellitus

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion Criteria: Confirmed continuous albuminuria
Exclusion criteria: Intake of any kind of vitamin supplements in recent months, Active urinary tract infections, increased liver enzymes more than 2 times, Allergic reactions to zinc, Failure to follow up, Any history of systemic inflammatory disorders or active infection, GFR below 30 ml / min, Hypogonadysm due to other reasons, Existence of proteinuria due to other reasons

Age

From **30 years** old to **70 years** old

Gender

Male

Phase
2
Groups that have been masked
No information
Sample size
Target sample size: **50**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Crossover
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Zanjan University of Medical Sciences, Ethical Committee
Street address
Azadi Boulevard
City
Zanjan
Postal code
77978-45157
Approval date
2009-07-29, 1388/05/07
Ethics committee reference number
1617/3-3/19

Health conditions studied

1

Description of health condition studied
Diabetic Nephropathy
ICD-10 code
E10, E11,
ICD-10 code description

Primary outcomes

1

Description
Microalbominuria
Timepoint
at the beginning of the study and 3 months after intervention
Method of measurement
Immuno Turbidomethry

Secondary outcomes

1

Description
Glomerular Filtration Rate
Timepoint
at the begining of the study and 3month after intervention
Method of measurement
Based on this formula:GFR=140-BW×Age/p×72

2

Description
Sexual Function
Timepoint
at the beginning of the study and 3month after intervention
Method of measurement
Based on IIEF-5 questionnaire

Intervention groups

1

Description
placebo for three months
Category
Placebo

2

Description
cap zinc sulfate : 30mg/daily for 3 months
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Endocrine Clinic of Zanjan, Vali -e-Asr Hospital
Full name of responsible person
Dr. Faranak Sharifi
Street address
Vali-e-Asr Hospital, Zanjan , Iran
City
Zanjan

Sponsors / Funding sources

1

Sponsor
Name of organization / entity

Zanjan Metabolic Diseases Research Center, Zanjan University of Medical Sciences

Full name of responsible person

Dr. Alireza Biglari

Street address

Azadi Boulevard

City

Zanjan

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Zanjan Metabolic Diseases Research Center, Zanjan 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

Zanjan Metabolic Diseases Research Center

Full name of responsible person

Dr. Faranak Sharifi

Position

Associate professor

Other areas of specialty/work

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MD

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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