

Clinical Trial Protocol

Iranian Registry of Clinical Trials

08 Jun 2026

Effect of Zinc sulfate consumption on serum Galectin-3 level in Diabetic Hemodialysis patients

Protocol summary

Study aim

Determine the effect of Zinc sulfate consumption on serum Galectin-3 level in diabetic Hemodialysis patients

Design

Randomized double-blind placebo clinical controlled trial

Settings and conduct

This study is double blind, placebo clinical controlled trial(Randomization and allocation will hide from the researcher and patients until the main analyses were completed). Diabetic hemodialysis patients form at the Imam Ali Dialysis Center (Zahedan, Iran) will randomly divided into 2 groups (case=20, control=20) to receive 220 mg Zinc sulfate (containing 50 mg zinc) supplements or placebo (220-mg corn starch). Blood samples were taken at baseline and after 56 days intervention to quantify serum galectin-3 level.

Participants/Inclusion and exclusion criteria

Inclusion criteria:Diabetic hemodialysis patients; Age:15-70 years; Pass at least 6 months from hemodialysis; Not having inflammatory diseases affecting on serum inflammatory markers; Not consuming supplements containing antioxidants, Zinc supplement, vitamins E and C supplements and Steroidal and Non-Steroidal Anti-Inflammatory drugs(NSAIDs) one month before the start of the study. Non-inclusion criteria: Consumption of Antibiotics or existence of infectious and feverish illnesses one month before starting the study; Existence of diseases affecting serum galectin-3 such as cardiovascular disease

Intervention groups

Intervention group1: Diabetic hemodialysis patients who will receive 220mg Zinc sulfate capsule (n=20) manufactured by Alhavi Pharmaceutical Company (Tehran, Iran), once a day for 56 days. Control-group:Diabetic hemodialysis patients (n=20) who will receive a placebo capsule (220mg corn starch) manufactured by Alhavi Pharmaceutical Company (Tehran, Iran), for 56 days.

Main outcome variables

Galectin-3

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20191217045765N1**

Registration date: **2020-02-09, 1398/11/20**

Registration timing: **retrospective**

Last update: **2020-02-09, 1398/11/20**

Update count: **0**

Registration date

2020-02-09, 1398/11/20

Registrant information

Name

Mansour Karajibani

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 54 3341 6797

Email address

mkarajibani@zaums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2019-12-22, 1398/10/01

Expected recruitment end date

2020-01-20, 1398/10/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of Zinc sulfate consumption on serum Galectin-3 level in Diabetic Hemodialysis patients

Public title

Effect of Zinc sulfate in Diabetic Hemodialysis patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Diabetic Hemodialysis patients Age:15-70 years old Pass at least 6 months from hemodialysis Not having inflammatory diseases affecting on serum inflammatory markers Not consuming supplements containing antioxidants, Zinc supplement, vitamins E and C supplements and Steroidal and Non-Steroidal Anti-Inflammatory drugs(NSAIDs) one month before the start of the study

Exclusion criteria:

Consumption of antibiotics or existence of infectious and feverish illnesses one month before starting the study Existence of diseases affecting serum galectin-3 such as cardiovascular disease

Age

From **20 years** old to **70 years** old

Gender

Both

Phase

3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **40**

Randomization (investigator's opinion)

Randomized

Randomization description

Diabetic Hemodialysis patients with inclusion criteria enter as available. Then they will be divided into two groups(case and control) using the file number through random variable.

Blinding (investigator's opinion)

Double blinded

Blinding description

Randomization and allocation will hide from the researcher and patients until the main analyses were completed

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethical Committee of Zahedan University of Medical Sciences

Street address

Dr Hesabi Sq; Khalije Fars Blvd; Zahedan; Iran.

City

Zahedan

Province

Sistan-va-Balouchestan

Postal code

9816743463

Approval date

2019-12-08, 1398/09/17

Ethics committee reference number

IR.ZAUMS.REC.1398.330

Health conditions studied

1

Description of health condition studied

Diabetic Hemodialysis

ICD-10 code

N18.6

ICD-10 code description

End stage renal disease

Primary outcomes

1

Description

Serum galectin-3

Timepoint

Before and after 8-week intervention

Method of measurement

It measured by ELISA method with standard kit

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group1: The zinc-supplementation group(n=20) will receive a 220-mg Zinc sulfate capsule (containing 50 mg zinc) manufactured by Alhavi Pharmaceutical Company (Tehran, Iran); for 56 days.

Category

Treatment - Drugs

2

Description

Control group: The control-group (n=20) will receive a placebo capsule (220-mg corn starch), for 56 days.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Ali Dialysis Center

Full name of responsible person

Dr Elham Shahraki

Street address

Imam Ali Hospital; Salamat Blvd; khaliye Fars High road

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98167-43111

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Dr Nour Mohammad Bakhshani

Street address

Dr Hesabi Sq; Khaliye Fars Blvd; Zahedan; Iran.

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Zahedan University of Medical Sciences

Proportion provided by this source

100

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

Dr mansour karajibani

Position

Faculty member

Latest degree

Ph.D.

Other areas of specialty/work

Nutrition

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Person responsible for updating data

Contact

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Razieh Hosseini

Position

MS.c of Nutrition

Latest degree

Bachelor

Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available