Clinical Trial Protocol
Iranian Registry of Clinical Trials

19 Sep 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
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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; khalije Fars High road

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Zahedan University of Medical Sciences

Full name of responsible person

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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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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