Clinical Trial Protocol
Iranian Registry of Clinical Trials

21 Jul 2026

Improvement of oxidative stress injuries following the supplementation of zinc in chronic hemodialysis patients

Protocol summary

Summary

The purpose of the present investigation was to examine the effect of Zn supplementation on the improvement of uremic symptoms (through improvement of oxidative stress) in chronic HD patients. In a double blind, randomized, controlled crossover trial, 73 chronic HD patients without exclusion criteria were randomized into following groups. The patients received placebo or 100 mg elemental zinc daily for 2 months. The patients were crossed over after 2 months washout period and received alternative treatments. Serum levels of zinc, total antioxidant capacity, total glutathione, superoxide dismutase activity, malondialdehyde, lipid profile, antiphosholipid, and blood sugar at the baseline and 60th, 120th, 180th days were determined. Moreover, neurological and hematological factors, ejection fraction, blood pressure, taste acuity, smell, libido, and pruritus were measured at above-mentioned intervals.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138902033777N1**
Registration date: **2003-10-10, 1382/07/18**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2003-10-10, 1382/07/18

Registrant information

Name

Mohammad Mazani

Name of organization / entity

Faculty of Medicine, Ardabil university of medical sciences,

Country

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Recruitment status

Recruitment complete

Funding source

Tabriz university of medical sciences

Expected recruitment start date

2003-10-10, 1382/07/18

Expected recruitment end date

2004-12-26, 1383/10/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Improvement of oxidative stress injuries following the supplementation of zinc in chronic hemodialysis patients

Public title

The effect of zinc supplementation in chronic hemodialysis patients

Purpose

Basic scienece

Inclusion/Exclusion criteria

Inclusion criteria: Hemodialysis more than 6 month, Age more than 20 year, referring to Tabriz Sina Hospital for hemodialysis Exclusion criteria: presence of gastrointestinal disorders, smoking, kidney transplantation candidates, lactation, pregnancy, consumption of glucocorticoids, antibiotics, penicilamine, estrogens or contraceptives (in females), hospitalization due to other reasons than chronic renal failure

Age

From **20 years** old

Gender

Both

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **73**

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

Drug Applied Research Center, Tabriz University of Medical Sciences

Street address

Drug Applied Research Center, Medical Research and Development Complex, Daneshgah St., Tabriz

City

Tabriz

Postal code

51656-65811

Approval date

2003-03-15, 1381/12/24

Ethics committee reference number

5/79/3295

Health conditions studied

1

Description of health condition studied

patients with hemodialsis

ICD-10 code

N00, N01,N

ICD-10 code description

Acute nephritic syndrome, Rapidly progressive nephritic syndrome, Chronic nephritic syndrome, Nephrotic syndrome, Unspecified nephritic syndrome, Glomerular disorders in diseases classified elsewhere, Acute renal failure, Chronic renal failure, Unspecifie

Primary outcomes

1

Description

serum level of zinc

Timepoint

Baseline and days 60, 120, and 180 after the intervention in each period

Method of measurement

as microgram per deciliter scale by atomic absorption spectrophotometry

2

Description

Serum total antioxidant capacity

Timepoint

Baseline and days 60, 120, and 180 after the intervention in each period

Method of measurement

as mM scale by spectrophotometry

3

Description

red blood cell superoxide dismutase activity

Timepoint

Baseline and days 60, 120, and 180 after the intervention in each period

Method of measurement

as unit per gram of hemoglobin scale by spectrophotometry

4

Description

serum total glutathione

Timepoint

Baseline and days 60, 120, and 180 after the intervention in each period

Method of measurement

as mM scale by spectrophotometry

5

Description

malondialdehyde (MDA)

Timepoint

Baseline and days 60, 120, and 180 after the intervention in each period

Method of measurement

as nmol/ml scale by spectrophotometry

6

Description

fasting serum glucose

Timepoint

Baseline and days 60, 120, and 180 after the intervention in each period

Method of measurement

as mg/dl scale by spectrophotometry

7

Description
Serum total cholesterol
Timepoint
4 time at 2 month interval at the 0th, 60th, 120th and 180th days of study (before and after intervention period, before and after placebo period)
Method of measurement
as mg/dl scale by spectrophotometry

8

Description
serum triglyceride
Timepoint
Baseline and days 60, 120, and 180 after the intervention in each period
Method of measurement
as mg/dl scale by spectrophotometry

9

Description
HDL cholesterol
Timepoint
Baseline and days 60, 120, and 180 after the intervention in each period
Method of measurement
as mg/dl scale by spectrophotometry

10

Description
LDL cholesterol
Timepoint
Baseline and days 60, 120, and 180 after the intervention in each period
Method of measurement
as mg/dl scale by spectrophotometry

11

Description
serum total lipid
Timepoint
Baseline and days 60, 120, and 180 after the intervention in each period
Method of measurement
as mg/dl scale by spectrophotometry

12

Description
Central and peripheral nerves evaluation
Timepoint
Baseline and days 60, 120, and 180 after the intervention in each period
Method of measurement
as m/s, ms and µv scales by electrodiagnostic test

13

Description
serum antiphospholipid
Timepoint
Baseline and days 60, 120, and 180 after the intervention in each period
Method of measurement
as u/ml by ELIZA

14

Description
cardiac ejection fraction
Timepoint
Baseline and days 60, 120, and 180 after the intervention in each period
Method of measurement
as % by echocardiography

15

Description
blood pressure
Timepoint
Baseline and days 60, 120, and 180 after the intervention in each period
Method of measurement
as mmHg by mercury manometer

Secondary outcomes

1

Description
taste perception evaluation
Timepoint
Baseline and days 60, 120, and 180 after the intervention in each period
Method of measurement
scale of taste acuity by taste tesing (Fernstrom A et al. Nephrol 1996 :45(3):169-74)

2

Description
pruritus evaluation
Timepoint
Baseline and days 60, 120, and 180 after the intervention in each period
Method of measurement
as pruritic score by pruritus questionnaire

3

Description
cell blood count (CBC) and diffraction
Timepoint
Baseline and days 60, 120, and 180 after the intervention in each period
Method of measurement
as number per microliter and % scale by Cell counter

4

Description

smell testing

Timepoint

Baseline and days 60, 120, and 180 after the intervention in each period

Method of measurement

smell test by pipe tobacco

5

Description

libido

Timepoint

Baseline and days 60, 120, and 180 after the intervention in each period

Method of measurement

by questionnaire

Intervention groups

1

Description

cornstarch, 2 capsules per day for 2 months

Category

Placebo

2

Description

zinc sulfates pentahydrate, two 220 mg capsules per day for 2 months

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sina Hospital

Full name of responsible person

kyghobad Niyazmand

Street address

Sina Hospital, Azadi street, Tabriz

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Drug Applied Research Center-Tabriz University of Medical Sciences

Full name of responsible person

Dr Mesgari

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City

Tabriz

Grant name

31303000

Grant code / Reference number

124203

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

Yes

Title of funding source

Drug Applied Research Center-Tabriz 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

Ardabil University of Medical sciences - faculty of medicine

Full name of responsible person

Mohammad Mazani

Position

PhD of clinical biochemistry, Assistant Professor

Other areas of specialty/work

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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