

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, antiphospholipid, 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

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Name of organization / entity

Faculty of Medicine, Ardabil university of medical sciences,

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Iran (Islamic Republic of)

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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 science

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, penicillamine, 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 hemodialysis

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 μ v 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 testing (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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Drug Applied Research Center - Medical Research and Development Complex Daneshgah St. Tabriz
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

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Position

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

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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