

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparison of zinc supplementation and plasebo on clinical improvement of severe head trauma patients admitted to ICU: A Randomized Clinical Trial

Protocol summary

Summary

This double-blind, randomized clinical trial has been done to determine the effects of zinc supplementation on clinical outcomes of patients with severe head trauma. The study was carried out in ICU of Shahid kamyab hospital of Mashhad. One hundred patients with severe head trauma, aged between 18 to 65 years and Glasgow outcome score (GSC) of 6 to 8 randomly allocated to either supplementation and placebo group. The groups receive 120 mg zinc (528 mg zinc sulfate) or placebo through enteral feeding for 15 days, respectively. Plasma zinc and copper, 24-hour urine zinc concentrations, plasma albumin, Sequential Organ Failure Assessment (SOFA), and GCS were assessed on day one, seven and sixteen. Erythrocyte sedimentation rate (ESR) and C-reactive protein (CRP), and White Blood Cell (WBC) count were measured on day one and sixteen. GCS and mortality rate were assessed on 28th day. The length of hospital stay and Glasgow Outcome Score (GOS) were calculated on hospital discharge day. All patients received enteral or parenteral feeding and gastric intolerance, amount of energy and protein were assessed during the study.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016053028176N1**
Registration date: **2016-06-23, 1395/04/03**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2016-06-23, 1395/04/03

Registrant information

Name

Maryam Khazdouz

Name of organization / entity

Mashhad University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 51 3882 8888

Email address

moshen@genetics.ac.cn

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Mashhad University of Medical Sciences

Expected recruitment start date

2012-08-22, 1391/06/01

Expected recruitment end date

2013-09-21, 1392/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of zinc supplementation and placebo on clinical improvement of severe head trauma patients admitted to ICU: A Randomized Clinical Trial

Public title

Effect of zinc supplementation on severe head trauma patients

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Severe head trauma patients; aged between 18 to 65 years; GCS between 6-8 Exclusion criteria: patients undergoing a craniotomy; or with a medical history of liver, respiratory or renal disease; diabetes; hypertension and cardiovascular diseases; blood clotting problems; cancer and ongoing pregnancy; patients with contraindication of enteral nutrition

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

method of random allocation of the study is using random number tables

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Mashhad University of Medical Sciences

Street address

Administration Center(Qoreishi Building) – Daneshgah St

City

Mashhad

Postal code

Approval date

2012-07-22, 1391/05/01

Ethics committee reference number

910055

Health conditions studied

1

Description of health condition studied

severe head trauma

ICD-10 code

(S00-S09)

ICD-10 code description

Injuries to the head

Primary outcomes

1

Description

Glasgow outcome score (GCS)

Timepoint

First 24 hours of admission, 7th, 16th and 28th day

Method of measurement

GCS table

2

Description

Sequential Organ Failure Assessment (SOFA)

Timepoint

First 24 h of admission, 7th and 16 th day

Method of measurement

SOFA table

3

Description

Zinc plasma concentrations

Timepoint

First 24 hours of admission, 7th and 16th day

Method of measurement

Atomic absorption spectrophotometer

4

Description

C-reactive protein (CRP)

Timepoint

First 24 hours of admission and 16th day

Method of measurement

CRP ELISA Kit

Secondary outcomes

1

Description

Copper plasma concentrations

Timepoint

first 24 hours of admission, 7th and 16th day

Method of measurement

Atomic absorption spectrophotometer

2

Description

length of hospital stay (LOS)

Timepoint

at discharge day

Method of measurement

number of hospitalization days

3

Description

Glasgow Outcome Score (GOS)

Timepoint

At hospital discharge day

Method of measurement

GOS table

4

Description

Erythrocyte sedimentation rate (ESR)

Timepoint

First 24 hours of admission and 16th day

Method of measurement

Centrifuged

5

Description

white blood cell (WBC) count

Timepoint

First 24 hours of admission and 16th day

Method of measurement

Conunt of WBC with cell counter

6

Description

Mortality rate

Timepoint

At hospital discharge day

Method of measurement

Conunt of patients (dead and alive)

7

Description

Enteral intake and parenteral administered

Timepoint

Daily

Method of measurement

Recods of amounts of intake

Intervention groups

1

Description

Intervention: 120 mg zinc elemental (528 mg zinc sulfat) as 20 ml zinc solution that were prepared by the study pharmacist in the Investigative Pharmacy Research Centre affiliated to Mashhad University of Medical Sciences Number of use: 2 times per day (10 ml at any time) for 15 days

Category

Treatment - Drugs

2

Description

Control: 20 ml distilled water that were prepared by the

study pharmacist in the Investigative Pharmacy Research Centre affiliated to Mashhad University of Medical Sciences Number of use: 2 times per day (10 ml at any time) for 15 days

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Kamyab Hospital in Mashhad

Full name of responsible person

Dr Mohamadeza Ehsaii

Street address

Fadaieyan Eslam Avenue, Nakhrisi Square

City

Mashhad

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Mashhad University of Medical Sciences

Full name of responsible person

Mohsen tafaghodi

Street address

Administration Center(Qoreishi Building) – Daneshgah St

City

Mashhad

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Vice chancellor for research, Mashhad 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

Faculty of Medicine, Mashhad University of Medical Sciences

Full name of responsible person

Mohamad safarian

Position

Associate Professor of Nutrition Sciences

Other areas of specialty/work

Street address

Pardis Alley, Azadi Square

City

Mashhad

Postal code

917794-8564

Phone

+98 51 3882 8888

Fax

Email

safarianM@mums.ac.ir

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Iran University of Medical Sciences

Full name of responsible person

Maryam khazdouz

Position

Msc of nutrition

Other areas of specialty/work

Street address

Shahid Hemmat Highway

City

Tehran

Postal code

1449614535

Phone

+98 45 3325 0610

Fax

Email

maryam.khazdouz@hotmail.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Iran University of Medical Science

Full name of responsible person

Maryam khazdouz

Position

PHD Student of nutrition

Other areas of specialty/work

Street address

Shahid Hemmat Highway

City

Tehran

Postal code

1449614535

Phone

+98 45 3325 0610

Fax

Email

Maryam.khazdouz@hotmail.com

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