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
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Iran (Islamic Republic of)
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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 plasebo 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 whit 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 randomly 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

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Person responsible for scientific inquiries

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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