

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

09 Jun 2026

### The effect of supplementation on reducing depression in children with cancer referred to the oncology ward of Bu Ali Sina Hospital in Sari

#### Protocol summary

##### Study aim

The effect of supplementation on reducing depression in children with cancer

##### Design

Non-randomized clinical trial assigned to intervention and control groups. with 75 samples

##### Settings and conduct

In children with malignancy who are on the verge of depression or depression according to the CDI test, they are treated with zinc by measuring zinc levels. In the group of patients with zinc deficiency, in addition to the standard treatment for depression, they are treated orally with 10 mg of zinc gluconate daily. In the group with normal zinc levels, the first group of patients with normal zinc levels receive 10 mg of zinc gluconate daily. In the second group, patients with normal zinc levels also receive only depression treatment. One month later, all three groups are tested for CDI. The project will be carried out in Bu Ali Hospital

##### Participants/Inclusion and exclusion criteria

Age between 7 and 18 years, suffering from chemotherapy-treated malignancy, not more than one month after the last dose of chemotherapy, not taking antidepressants of any category during the past month, not taking zinc supplements or other supplements  
Contains zinc compounds during the past month, consent to fill out a questionnaire, regular use of antidepressants or zinc

##### Intervention groups

Intervention group: In addition to the standard treatment for depression, the group of patients with zinc deficiency will receive oral treatment with 10 mg of zinc gluconate daily at the discretion of the intervention group: Group with normal zinc level The first group of patients in normal zinc level receive 10 mg of zinc gluconate daily child psychiatrist. Control group: The second group of patients with normal zinc levels also receive only depression treatment and do not receive zinc supplements

#### Main outcome variables

Depression score based on CDI tes

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20190202042583N1**

Registration date: **2020-08-14, 1399/05/24**

Registration timing: **registered\_while\_recruiting**

Last update: **2020-08-14, 1399/05/24**

Update count: **0**

##### Registration date

2020-08-14, 1399/05/24

##### Registrant information

##### Name

Mohammad Naderisorki

##### Name of organization / entity

##### Country

Iran (Islamic Republic of)

##### Phone

+98 11 3334 7837

##### Email address

dr.naderisorki@mazums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2019-03-22, 1398/01/02

##### Expected recruitment end date

2020-09-21, 1399/06/31

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

**Trial completion date**

empty

**Scientific title**

The effect of supplementation on reducing depression in children with cancer referred to the oncology ward of Bu Ali Sina Hospital in Sari

**Public title**

The effect of supplementation on reducing depression in children with cancer

**Purpose**

Treatment

**Inclusion/Exclusion criteria****Inclusion criteria:**

Age between 7 to 18 years Having malignancy treated with chemotherapy Not more than one month has passed since the last round of chemotherapy Do not take antidepressants of any category during the past month Do not take zinc supplements or other supplements containing zinc compounds during the past month Satisfaction to test the serum level by taking a blood sample Regular use of antidepressants or zinc supplements

**Exclusion criteria:**

Congenital diseases of zinc metabolism such as acrodermatitis enteropathy, chronic inflammatory bowel disease, malabsorption syndromes

**Age**

From **7 years** old to **18 years** old

**Gender**

Both

**Phase**

3

**Groups that have been masked**

*No information*

**Sample size**

Target sample size: **75**

**Randomization (investigator's opinion)**

Not randomized

**Randomization description****Blinding (investigator's opinion)**

Not blinded

**Blinding description****Placebo**

Not used

**Assignment**

Parallel

**Other design features****Secondary Ids**

empty

**Ethics committees****1****Ethics committee****Name of ethics committee**

committee of Mazandaran University of Medical Sciences.

**Street address**

Central Headquarters of Mazandaran University of Medical Sciences, at the beginning of Valiasr Highway, Joibar Three Ways, Imam Square, Sari

**City**

sari

**Province**

Mazandaran

**Postal code**

۴۸۱۵۷۳۳۹۷۱

**Approval date**

2019-12-18, 1398/09/27

**Ethics committee reference number**

IR.MAZUMS.REC.1398.1182

**Health conditions studied****1****Description of health condition studied**

Depression in pediatric patients with malignancy

**ICD-10 code**

F06.3

**ICD-10 code description**

Mood disorder due to known physiological condition

**Primary outcomes****1****Description**

Depression score based on the Mariaquas Children Depression Inventory "CDI"

**Timepoint**

day 30

**Method of measurement**

CDI test

**Secondary outcomes**

empty

**Intervention groups****1****Description**

Intervention group: In addition to the standard treatment for depression, the group of patients with zinc deficiency will receive oral treatment with 10 mg of zinc gluconate daily at the discretion of the child psychiatrist.

**Category**

Treatment - Drugs

**2****Description**

Intervention group: Group with normal zinc level The first group of patients in normal zinc level receive 10 mg of zinc gluconate daily

**Category**

Treatment - Drugs

### 3

#### Description

Control group: The second group of patients with normal zinc levels also receive only depression treatment and do not receive zinc supplements

#### Category

Treatment - Drugs

### Recruitment centers

#### 1

##### Recruitment center

###### Name of recruitment center

Bo Ali Sina Hospital in Sari

###### Full name of responsible person

Mohamad Naderi Soraki

###### Street address

Sari. The beginning of Ghaem Shahr road. Bu Ali Sina Hospital

###### City

Sari

###### Province

Mazandaran

###### Postal code

۳۳۹۷۱۴۸۱۵۷

###### Phone

+98 11 3304 4001

###### Email

publicrel@mazums.ac.ir

### Sponsors / Funding sources

#### 1

##### Sponsor

###### Name of organization / entity

Mazandaran University of Medical Sciences

###### Full name of responsible person

Dr. Majid Saeedi

###### Street address

ساری. میدان معلم. طبقه پایین دارو خانه 13 آبان

###### City

sari

###### Province

Mazandaran

###### Postal code

۴۸۱۵۷۳۳۹۷۱

###### Phone

+98 11 3325 7230

###### Email

pajhooheshi@mazums.ac.ir

###### Grant name

###### Grant code / Reference number

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

Yes

###### Title of funding source

Mazandaran 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

Mazandaran University of Medical Sciences

##### Full name of responsible person

Mohammad Naderi Soraki

##### Position

Associate professor

##### Latest degree

Subspecialist

##### Other areas of specialty/work

Pediatrics

##### Street address

Headquarters of Mazandaran University of Medical Sciences. At the beginning of Valiasr Highway.Sari

##### City

Sari

##### Province

Mazandaran

##### Postal code

4815733971

##### Phone

+98 11 3304 4001

##### Email

dr.naderisorki@mazums.ac.ir

### Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Mazandaran University of Medical Sciences

##### Full name of responsible person

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**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

**Study Protocol**

No - There is not a plan to make this available

**Statistical Analysis Plan**

No - There is not 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**

Not applicable

**Analytic Code**

Not applicable

**Data Dictionary**

Undecided - It is not yet known if there will be a plan to make this available

**Title and more details about the data/document**

Only part of the data, such as information about the main outcome or the like, can be shared

**When the data will become available and for how long**

Start the access period 6 months after printing the results

**To whom data/document is available**

Researchers working in academic and scientific institutions

**Under which criteria data/document could be used**

Researchers working in academic and scientific institutions

**From where data/document is obtainable**

Email to dr.naderisorki@mazums.ac.ir

**What processes are involved for a request to access data/document**

After communicating with the email if available, data and results will be available

**Comments**