

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

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+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

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+98 11 3325 7230

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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

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Person responsible for scientific inquiries

Contact

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Person responsible for updating data**Contact****Name of organization / entity**

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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