

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

Assessment the effect of overshadowing on control of chemotherapy-induced nausea and vomiting in children with leukemia

Protocol summary

Study aim

determination the effect of overshadowing on control of chemotherapy-induced nausea and vomiting in children with leukemia

Design

This study is a Non-randomized clinical trial. Samples are 200 children with leukemia and undergoing chemotherapy in Mofid hospital. The allocation of selected individuals in the intervention and control groups will be based on even days (intervention group) and odds days (control group).

Settings and conduct

First, in both groups, before the start of each course of chemotherapy, the severity of nausea through VAS and vomiting will be assessed by recording the number of cases. In the intervention group, in addition to routine procedures, 10 minutes before the start of chemotherapy, a flavored candy is given to the child, which is repeated during three courses of chemotherapy. To avoid the possible effect of taste, the taste of candy changes with each injection. At the end of each course of chemotherapy, the rate of nausea and vomiting is recorded in both groups.

Participants/Inclusion and exclusion criteria

Inclusion criteria are: 1. Willingness to participate in the study and written consent 2. Age 3 to 18 years 3. Being diagnosed with Leukemia 4. Undergoing chemotherapy 5. Existence of gag reflex (gagging) and ability to swallow Exclusion criteria: 1. Tumor metastasis to the central nervous system (CNS) or gastrointestinal tract 2. Consciousness disorders 3. Inability to eat by mouth (NPO) 4. Having other underlying and chronic diseases

Intervention groups

Both groups will routinely receive anti-nausea medication. In the intervention group, flavored candies will be used as an intervention in three courses of chemotherapy and the rate of nausea and vomiting will be measured before and after. In the control group, only the rate of nausea and vomiting, in three courses of

chemotherapy will be measured.

Main outcome variables

rate of nausea and vomiting

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20211004052665N1**

Registration date: **2021-11-14, 1400/08/23**

Registration timing: **registered_while_recruiting**

Last update: **2021-11-14, 1400/08/23**

Update count: **0**

Registration date

2021-11-14, 1400/08/23

Registrant information

Name

Ali Omidi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 21 0000 0000

Email address

aliomidi978@yahoo.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2021-11-05, 1400/08/14

Expected recruitment end date

2022-02-18, 1400/11/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date
empty

Scientific title
Assessment the effect of overshadowing on control of chemotherapy-induced nausea and vomiting in children with leukemia

Public title
the effect of overshadowing on control of chemotherapy-induced nausea and vomiting

Purpose
Prevention

Inclusion/Exclusion criteria
Inclusion criteria:
Undergoing chemotherapy Being diagnosed with Leukemia Existence of gag reflex (gagging) and ability to swallow Age 3 to 18 years
Exclusion criteria:
Tumor metastasis to the central nervous system (CNS) or gastrointestinal tract (to eliminate organic and organic causes of nausea and vomiting) Consciousness disorders Inability to eat by mouth (NPO) Having other underlying and chronic diseases

Age
From **3 years** old to **18 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **200**

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

Ethics Committee of Shahid Beheshti University of Medical Sciences

Street address

No 4, Moghaddam deadlock, South Ramin Ave, East Ferdows Blvd

City

Tehran

Province

Tehran

Postal code

1481999586

Approval date

2021-09-24, 1400/07/02

Ethics committee reference number

IR.SBMU.PHARMACY.REC.1400.131

Health conditions studied

1

Description of health condition studied

overshadowing

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

The rate of nausea

Timepoint

Before and after chemotherapy and repeated for three periods

Method of measurement

visual Analogue scale (VAS)

2

Description

Number of cases of vomiting

Timepoint

Before and after chemotherapy and repeated for three periods

Method of measurement

Table of records of the number of vomiting events

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In addition to routine procedures that is injecting ondansetron anti-nausea medication to the child, 10 minutes before the start of chemotherapy, a flavored candy is given to the child, which is repeated during three courses of chemotherapy. To avoid the possible effect of taste, the taste of candy changes with each injection.

Category

N/A

2

Description

Control group: Patients in the control group will not have any intervention and only in each chemotherapy courses, their nausea and vomiting will be measured and like the intervention group, routine procedures (injection of ondansetron anti-nausea medication) will be performed for them

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Mofid Hospital

Full name of responsible person

Ali Omid

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No 4, Moghaddam deadlock, South Ramin Ave, East Ferdows Blvd

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aliomidi978@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Ali Omid

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Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti 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

Shahid Beheshti University of Medical Sciences

Full name of responsible person

Ali Omid

Position

Msc student

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti University of Medical Sciences

Full name of responsible person

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Position

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Latest degree

Bachelor

Other areas of specialty/work

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

Shahid Beheshti 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

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/documentAll potential data is segmented after unrecognizable
individuals in the form of a thesis or article**When the data will become available and for how long**

Access period starts from 2022

To whom data/document is available

It will be available to everyone

Under which criteria data/document could be used

Researchers are licensed by the Research Committee

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two weeks by sending an email to the person in charge.**Comments**