Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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 Omidi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Shahid Beheshti University of Medical Sciences

Full name of responsible person
Ali Omidi

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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 Omidi

Position
Msc student

Latest degree
Bachelor

Other areas of specialty/work
Nursery

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Position
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Latest degree
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Person responsible for updating data

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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/document
All 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
From where data/document is obtainable
After publishing the article, visit the magazine site For more information, write to aliomidi978@yahoo.com
What processes are involved for a request to access data/document
Researchers can receive the necessary response after two weeks by sending an email to the person in charge.
Comments