

Clinical Trial Protocol

Iranian Registry of Clinical Trials

02 Jun 2026

The effect of intravenous Vitamin B6 administration in Prevention of chemotherapy induced nausea and vomiting in children with malignancy.

Protocol summary

Study aim

Determine the role of vitamin B6 in the treatment of nausea and vomiting due to chemotherapy

Design

Triple blind clinical trials and In the first stage, they receive vitamin B6 and in the next stage receive placebo.

Settings and conduct

This study will be conducted as a triple blind clinical trial in children with malignancy undergoing chemotherapy in Amirkabir Hospital in Arak. A total of 100 patients undergoing chemotherapy due to malignancy are included in the study. Blinding will performed by the head nurse of blood ward and takes the amount of vitamin B6 and distilled water and preserves, it as a medicine A = vitamin B6 and B = distilled water. The nurse and therapist do not know the type of drug. In the sample, we examine how chemotherapy has been used in these two cycles to cure nausea and vomiting, as well as severity.

Participants/Inclusion and exclusion criteria

Children with malignancy who are undergoing chemotherapy and referred to Amirkabir Hospital in Arak

Intervention groups

Patients in one step of study 6 hours before chemotherapy receive vitamin B6 and in another step receive placebo with the same dose.

Main outcome variables

nausea and vomiting.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20150119020715N8**

Registration date: **2018-07-22, 1397/04/31**

Registration timing: **retrospective**

Last update: **2018-07-22, 1397/04/31**

Update count: **0**

Registration date

2018-07-22, 1397/04/31

Registrant information

Name

Aziz Eghbali

Name of organization / entity

دانشگاه علوم پزشکی اراک

Country

Iran (Islamic Republic of)

Phone

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Email address

dr.eghbali@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2017-04-21, 1396/02/01

Expected recruitment end date

2017-12-21, 1396/09/30

Actual recruitment start date

2017-04-21, 1396/02/01

Actual recruitment end date

2017-12-21, 1396/09/30

Trial completion date

empty

Scientific title

The effect of intravenous Vitamin B6 administration in Prevention of chemotherapy induced nausea and vomiting in children with malignancy.

Public title

The effect of intravenous Vitamin B6 administration in Prevention of nausea and vomiting due to chemotherapy in pediatrics.

Purpose

Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
desire to participate in the study Children with malignancy who need to chemotherapy 2 to 15 years of age
Exclusion criteria:
Unwilling to participate in the study patients with Immune deficiency patients with cardiovascular disease patients with AIDS patients with renal failure patients with diabetes

Age
From **2 years** old to **15 years** old

Gender
Both

Phase
3

Groups that have been masked

- Care provider
- Investigator
- Data analyser

Sample size
Target sample size: **100**
Actual sample size reached: **100**
Randomization (investigator's opinion)
Not randomized

Randomization description
Blinding (investigator's opinion)
Triple blinded

Blinding description
Clinical care will be blind of the type of medication. Researchers are also blind of the grouping. Data analyzer is also blind of the grouping.

Placebo
Used

Assignment
Crossover

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee of Arak University of Medical Sciences
Street address
Arak University of Medical Sciences, Sardasht, Arak, Iran
City
Arak
Province
Markazi
Postal code
38481769411

Approval date
2017-03-06, 1395/12/16
Ethics committee reference number
IR.ARAKMU.REC.1395.443

Health conditions studied

1

Description of health condition studied
nausea and vomiting
ICD-10 code
R11.2
ICD-10 code description
Nausea with vomiting, unspecified

Primary outcomes

1

Description
nausea and vomiting
Timepoint
The frequency of nausea and vomiting is recorded within 24 hours.
Method of measurement
Recorded in checklist.

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In a cycle of chemotherapy for the patient, in addition to the use of Granisetron (3 mg / 3 ml), injected into the sample for a half-hour before the chemotherapy was given intravenously vitamin B6 (in the age group of 2-5 years 100 mg - 5-10 years 200 mg - over 10 years 300 mg) 6 hours before chemotherapy is given to an individual.
Category
Treatment - Drugs

2

Description
Control group: In the next cycle of chemotherapy, the same patient as the same previous chemotherapy drug, in addition to the Granisetron, was used as placebo in the same dose of distilled water, and the distilled water was injected intravenously 6 hours before chemotherapy.
Category
Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Department of Pediatrics, Amir Kabir Hospital

Full name of responsible person

Aziz Eghbali

Street address

Amir Kabir Hospital, Alamolhoda street, Arak, Iran

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dr.eghbali@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Mohammad arjomandzadegan

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3819693345, Vice Chancellor for Research, Arak
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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

Arak 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**

Arak University of Medical Sciences

Full name of responsible person

Dr Aziz Eghbali

Position

Faculty, Pediatrics Oncologist

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

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Person responsible for scientific inquiries

Contact**Name of organization / entity**

Arak University of Medical Sciences

Full name of responsible person

Dr Aziz Eghbali

Position

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD

Participants information will remain confidential

Study Protocol

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

Statistical Analysis Plan

Undecided - It is not yet known if there will be 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

No - There is not a plan to make this available

Analytic Code

No - There is not a plan to make this available

Data Dictionary

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