Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 2026

Evaluation of intravenous Vitamin B6 administration in chemotherapy induced nausea and vomiting in children suffering from malignancy

Protocol summary

Study aim
Evaluation of intravenous Vitamin B6 administration on chemotherapy induced nausea and vomiting in children suffering from malignancy

Design
This study will be conducted as a triple-blind clinical trials in children with malignancy undergoing chemotherapy in Amir Kabir Hospital in Arak. A total of 100 patients undergoing chemotherapy due to malignancy are included in the study.

Settings and conduct
This study will be conducted as a triple-blind clinical trials in children with malignancy undergoing chemotherapy in Amir Kabir Hospital in Arak.

Participants/Inclusion and exclusion criteria
Inclusion criteria: over 2 years old; both gender; children with malignancy Exclusion criteria: Dissatisfaction to participate in the study

Intervention groups
Intervention group: In intervention group, patients are provided by Granisteron, 3 milligram in 3 milliliter, intravenously, 30 minutes before chemotherapy and vitamin B6 100 mg in 2-5 year age group, 200 mg in 5-10 year age group and 300 mg in over 10 year age group, intravenously, 6 hours before chemotherapy. In next chemotherapy cycle in same patients, they are provided by Granisteron, 3 milligram in 3 milliliter, intravenously, 30 minutes before chemotherapy and normal saline every 6 hours before chemotherapy.

Main outcome variables
Nausea; vomiting

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20141209020258N67**
Registration date: **2018-02-16, 1396/11/27**
Registration timing: **registered_while_recruiting**

Last update: **2018-02-16, 1396/11/27**
Update count: **0**

Registration date
2018-02-16, 1396/11/27

Registrant information

Name
Fariba Farokhi

Name of organization / entity
Arak University of Medical Sciences

Country
Iran (Islamic Republic of)

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+98 86 3222 2003

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f.farokhi@arakmu.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-03-10, 1395/12/20

Expected recruitment end date
2019-03-11, 1397/12/20

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date
empty

Scientific title
Evaluation of intravenous Vitamin B6 administration in chemotherapy induced nausea and vomiting in children suffering from malignancy

Public title
Effect of intravenous Vitamin B6 administration in

chemotherapy induced nausea and vomiting

Purpose

Diagnostic

Inclusion/Exclusion criteria

Inclusion criteria:

being at the age of 2 to 5 years both gender Children with malignancy

Exclusion criteria:

Dissatisfaction to participate in the study

Age

From **2 years** old to **5 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

N/A

Randomization description

Blinding (investigator's opinion)

Triple blinded

Blinding description

Participant and Analyzer are blind.

Placebo

Used

Assignment

Single

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

Vice chancellor for research, Payambar azam complex, Basij squre, Sardasht, Arak

City

Arak

Province

Markazi

Postal code

3814957558

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

chemotherapy in children

ICD-10 code

T80.810

ICD-10 code description

Extravasation of vesicant antineoplastic chemotherapy

Primary outcomes

1

Description

Nausa

Timepoint

From beginning to the end of the chemotherapy session

Method of measurement

questionnaire

2

Description

vomitting

Timepoint

From beginning to the end of the chemotherapy session

Method of measurement

questionnaire

3

Description

Severity of nausea and vomiting

Timepoint

From beginning to the end of the chemotherapy session

Method of measurement

questionnaire

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: In intervention group, patients are provided by Granisteron, 3 milligram in 3 milliliter, intravenously, 30 minutes before chemotherapy and vitamin B6 100 mg in 2-5 year age group, 200 mg in 5-10 year age group and 300 mg in over 10 year age group, intravenously, 6 hours before chemotherapy. In next chemotherapy cycle in same patients, they are provided by Granisteron, 3 milligram in 3 milliliter, intravenously, 30 minutes before chemotherapy and normal saline every 6 hours before chemotherapy.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Amirkabir hospital
Full name of responsible person
Dr Noshin Sajadi
Street address
Amirkabir hospital, Parastar square
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sajadi@arakmu.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Arak University of Medical Sciences
Full name of responsible person
Dr Aliarash Anoshirvani
Street address
Vice chancellor for research, Payambar Azam Complex, Basij square, Sardasht, Arak
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Grant name

empty

Grant code / Reference number

empty

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
Assistant professor
Latest degree
Subspecialist
Other areas of specialty/work
Pediatrics
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Person responsible for scientific inquiries

Contact

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Assistant of professor
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Person responsible for updating data

Contact

Name of organization / entity
Arak University of Medical Sciences

Full name of responsible person
Arefeh Adelnia

Position
دانشجوی پزشکی

Latest degree
Medical doctor

Other areas of specialty/work
General Practitioner

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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
When we publish relevant article in a journal.

When the data will become available and for how long
After publishing the article

To whom data/document is available
researchers who work at university

Under which criteria data/document could be used
If there are additional questions

From where data/document is obtainable
Dr Sajadi

What processes are involved for a request to access data/document
They have to send their request to the professor who is the chair of the work and they also must pass administrative process of the university.

Comments