# Clinical Trial Protocol
# Iranian Registry of Clinical Trials

08 Nov 2026

## Evaluation of the effect of injectable vitamin B6 and vitamin C on reducing chemotherapy-induced nausea in solid cancer

### Protocol summary

**Study aim**
Evaluation of the effect of injectable vitamin B6 and Vitamin C on the reduction of chemotherapy-induced nausea in patients with solid cancer

**Design**
Quasi-experimental interventional study

**Settings and conduct**
This study will be conducted on a single group of 44 patients with solid tumors undergoing chemotherapy at Firoozgar Hospital, all of whom will provide informed consent. In this group, during the first chemotherapy cycle, a placebo will be administered six hours prior to chemotherapy infusion, alongside standard antiemetic medications. Both acute nausea (assessed two hours post-infusion) and delayed nausea (assessed 1 to 5 days post-infusion) will be evaluated. In the same patients, serving as their own controls, prior to the second chemotherapy cycle, 300 mg of Vitamin B6 and 1 g of Vitamin C will be administered intravenously in addition to standard antiemetic medications. Acute nausea (two hours post-infusion) and delayed nausea (1 to 5 days post-infusion) will be assessed again.

**Participants/Inclusion and exclusion criteria**
Patients with solid cancer under chemotherapy

**Intervention groups**
Control group: Patients receive a placebo prior to the first cycle of chemotherapy. Intervention group: The same patients receive intravenous Vitamin C and Vitamin B6 prior to the second cycle of chemotherapy.

**Main outcome variables**
Severity of early and delayed nausea

### General information

**Reason for update**

**Acronym**

**IRCT registration information**
IRCT registration number: **IRCT20251216068360N1**
Registration date: **2026-05-06, 1405/02/16**
Registration timing: **prospective**

Last update: **2026-05-06, 1405/02/16**
Update count: **0**

**Registration date**
2026-05-06, 1405/02/16

**Registrant information**

**Name**
Ali Mahdi zadeh

**Name of organization / entity**

**Country**
Iran (Islamic Republic of)

**Phone**
+98 21 6681 4038

**Email address**
alimhdzd1999@gmail.com

**Recruitment status**
**recruiting**

**Funding source**

**Expected recruitment start date**
2026-05-17, 1405/02/27

**Expected recruitment end date**
2027-06-17, 1406/03/27

**Actual recruitment start date**
empty

**Actual recruitment end date**
empty

**Trial completion date**
empty

**Scientific title**
Evaluation of the effect of injectable vitamin B6 and vitamin C on reducing chemotherapy-induced nausea in solid cancer

**Public title**
Evaluation of the effect of injectable vitamin B6 and vitamin C on reducing chemotherapy-induced nausea in

solid cancer patients referred to Firoozgar Hospital in 2025.

**Purpose**

Supportive

**Inclusion/Exclusion criteria**

**Inclusion criteria:**

patients with solid cancer who are under chemotherapy

**Exclusion criteria:**

Known hypersensitivity or allergic reaction to Vitamin B6 or Vitamin C Any change in chemotherapy regimen between the first and second cycles Severe renal impairment (eGFR < 30 mL/min/1.73 m²) or history of recurrent nephrolithiasis Severe hepatic impairment Concurrent use of non-standard antiemetic regimens or high-dose vitamin supplements Pregnancy or breastfeeding Symptomatic brain metastases or other causes of nausea and vomiting unrelated to chemotherapy Uncontrolled nausea and vomiting prior to initiation of the study (baseline instability)

**Age**

No age limit

**Gender**

Both

**Phase**

4

**Groups that have been masked**

- Participant

**Sample size**

Target sample size: **42**

**Randomization (investigator's opinion)**

Not randomized

**Randomization description**

**Blinding (investigator's opinion)**

Single blinded

**Blinding description**

This study is conducted using a single-blind design. The participants are blinded to their allocation into the intervention and control groups, while the investigators are aware of the assigned interventions. Group allocation is carried out using coded labels, and information regarding group assignment is withheld from participants until the completion of outcome assessment.

**Placebo**

Used

**Assignment**

Crossover

**Other design features**

## Secondary Ids

empty

## Ethics committees

### 1

**Ethics committee**

**Name of ethics committee**

Research Ethics Committees of School of Medicine

**Street address**

Iran University of Medical Sciences (IUMS), Shahid Hemmat Highway, Tehran, IRAN

**City**

Tehran

**Province**

Tehran

**Postal code**

۱۴۴۹۶۱۴۵۳۵

**Approval date**

2025-05-27, 1404/03/06

**Ethics committee reference number**

IR.IUMS.FMD.REC.1404.119

## Health conditions studied

### 1

**Description of health condition studied**

Chemothetrapy induced nausea in solid cancer patients

**ICD-10 code**

R11

**ICD-10 code description**

Nausea and vomiting

## Primary outcomes

### 1

**Description**

Severity of chemotherapy induced nausea on the basis of MAT Questionnaire

**Timepoint**

24 hours and 72 hours after intervention

**Method of measurement**

by the use of The Multinational Association of Supportive Care in Cancer (MASCC) Antiemesis Tool (MAT).

## Secondary outcomes

empty

## Intervention groups

### 1

**Description**

Intervention group: Injection of placebo 6 hours before first cycle of chemotherapy beside other usual Antiemetics and evaluation of early and delayed nausea in all patients.

**Category**

Placebo

### 2

**Description**

Control group: Injection of 300mg Vitamin B6 and 1gr Vitamin C IV beside other usual antiemetics and evaluation of early and delayed nausea in the same patients.

**Category**

Treatment - Drugs

## Recruitment centers

**1**

**Recruitment center**

**Name of recruitment center**
Firoozgar hospital

**Full name of responsible person**
Aliarash Anooshirvani

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## Sponsors / Funding sources

**1**

**Sponsor**

**Name of organization / entity**
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**Full name of responsible person**
علی امینی

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+98 21 8670 2503

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info@iums.ac.ir

**Grant name**

**Grant code / Reference number**

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

**Title of funding source**
Iran 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**
دانشگاه علوم‌پزشکی ایران

**Full name of responsible person**
علی آرش انوشیروانی

**Position**
Associate professor

**Latest degree**
Subspecialist

**Other areas of specialty/work**
Hematology

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## Person responsible for scientific inquiries

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## Person responsible for updating data

**Contact**

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General Practitioner

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## Sharing plan

**Deidentified Individual Participant Data Set (IPD)**

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

**Study Protocol**

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

**Statistical Analysis Plan**

Not applicable

**Informed Consent Form**

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

**Clinical Study Report**

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

**Analytic Code**

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

**Data Dictionary**

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