

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

10 Jun 2026

### Comparison of the effect of Dexamethasone with Ondansetron on nausea and vomiting in adults undergoing upper GI endoscopy

#### Protocol summary

##### Study aim

Comparison of the effect of dexamethasone and ondansetron on nausea and vomiting after upper gastrointestinal endoscopy in adults

##### Design

single-blinded randomized controlled clinical trial with parallel groups, phase 3 trial on 102 patients, randomization list through [www.sealedenvelope.com](http://www.sealedenvelope.com)

##### Settings and conduct

Patients of groups I and II of the ASA criterion who are candidates for upper gastrointestinal endoscopy will be randomly divided into 3 groups: receiving dexamethasone, ondansetron and the control group. Before upper gastrointestinal endoscopy, when the level of anesthesia is sufficient, 8 mg of dexamethasone will be injected intravenously to the patients in the dexamethasone group and 4 mg of intravenous ondansetron will be injected to the patients in the ondansetron group, and the patients in the control group will receive an equal volume of normal saline.

##### Participants/Inclusion and exclusion criteria

Patients 18 to 70 years who are candidates for endoscopy, with no history of sensitivity to the drugs used in the study, no history of chemotherapy and malignancy, and no use of anti-nausea and vomiting drugs up to 24 hours before the study

##### Intervention groups

Intervention group (dexamethasone): receiving 8mg of dexamethasone intravenously Intervention group (ondansetron): receiving 4mg of ondansetron intravenously Control group: receiving normal saline

##### Main outcome variables

Nausea and vomiting, cough, sore throat

#### General information

##### Reason for update

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20230926059530N1**

Registration date: **2023-10-24, 1402/08/02**

Registration timing: **registered\_while\_recruiting**

Last update: **2023-10-24, 1402/08/02**

Update count: **0**

##### Registration date

2023-10-24, 1402/08/02

##### Registrant information

###### Name

Ali Zamanian

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 31 4251 0991

###### Email address

alizamanian9674@gmail.com

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2023-10-06, 1402/07/14

##### Expected recruitment end date

2023-11-05, 1402/08/14

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of the effect of Dexamethasone with Ondansetron on nausea and vomiting in adults undergoing upper GI endoscopy

##### Public title

Comparison of the effect of Dexamethasone with Ondansetron on nausea and vomiting in adults undergoing upper GI endoscopy

### **Purpose**

Prevention

### **Inclusion/Exclusion criteria**

#### **Inclusion criteria:**

All patients between 18 and 70 years of age, group I and II criteria of ASA candidate for elective UGIE diagnosis based on the opinion of a gastroenterologist

#### **Exclusion criteria:**

No history of allergy to the drugs used in the study No history of chemotherapy Not receiving any anti-nausea medication 24 hours before endoscopy No history of malignancy

### **Age**

From **18 years** old to **70 years** old

### **Gender**

Both

### **Phase**

3

### **Groups that have been masked**

*No information*

### **Sample size**

Target sample size: **102**

### **Randomization (investigator's opinion)**

Randomized

### **Randomization description**

Patients will be randomly assigned to three groups receiving ondansetron, dexamethasone and the control group using the six block method and using the randomization list taken from the website [www.sealedenvelope.com](http://www.sealedenvelope.com).

### **Blinding (investigator's opinion)**

Not blinded

### **Blinding description**

### **Placebo**

Used

### **Assignment**

Parallel

### **Other design features**

## **Secondary Ids**

empty

## **Ethics committees**

### 1

#### **Ethics committee**

##### **Name of ethics committee**

Ethics committee of Kashan University of Medical Sciences

##### **Street address**

Qutb Ravandi Boulevard - Kashan University of Medical Sciences

##### **City**

Kashan

##### **Province**

Isfahan

##### **Postal code**

8715981151

### **Approval date**

2023-08-13, 1402/05/22

### **Ethics committee reference number**

IR.KAUMS.MEDNT.REC.1402.123

## **Health conditions studied**

### 1

#### **Description of health condition studied**

Diseases of the digestive system

#### **ICD-10 code**

K00-K93

#### **ICD-10 code description**

Diseases of the digestive system

## **Primary outcomes**

### 1

#### **Description**

nausea and vomiting

#### **Timepoint**

After upper gastrointestinal endoscopy

#### **Method of measurement**

Patient self-expression

### 2

#### **Description**

cough

#### **Timepoint**

After upper gastrointestinal endoscopy

#### **Method of measurement**

Patient self-expression

### 3

#### **Description**

Sore throat

#### **Timepoint**

After upper gastrointestinal endoscopy

#### **Method of measurement**

Patient self-expression

## **Secondary outcomes**

empty

## **Intervention groups**

### 1

#### **Description**

Intervention group: Receive 8mg of intravenous dexamethasone before upper gastrointestinal endoscopy

#### **Category**

Prevention

## 2

### Description

Intervention group: Receive 8mg of intravenous Ondansetron before upper gastrointestinal endoscopy

### Category

Prevention

## 3

### Description

Control group: Receiving normal saline before upper gastrointestinal endoscopy

### Category

Placebo

## Recruitment centers

### 1

#### Recruitment center

##### Name of recruitment center

Kashan Shahid Beheshti Hospital

##### Full name of responsible person

Ali Zamanian Najafabadi

##### Street address

Kashan Shahid Beheshti Hospital., Pezeshk Blvd., Qutb Rawandi Blvd., Kashan Town, . Isfahan, . Iran

##### City

Kashan

##### Province

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##### Postal code

8715981151

##### Phone

+98 31 5558 9227

##### Email

beheshtihospital@kaums.ac.ir

## Sponsors / Funding sources

### 1

#### Sponsor

##### Name of organization / entity

Kashan University of Medical Sciences

##### Full name of responsible person

Dr. Gholamali Hamidi

##### Street address

University of Medical Sciences., Pezeshk Blvd., Qutb Rawandi Blvd., Kashan Town, . Isfahan, . Iran

##### City

Kashan

##### Province

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##### Postal code

8715988141

##### Phone

+98 31 5558 9399

##### Email

research@kaums.ac.ir

##### Grant name

##### Grant code / Reference number

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

Yes

##### Title of funding source

Kashan 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

Kashan University of Medical Sciences

##### Full name of responsible person

Ali Zamanian Najafabadi

##### Position

Student

##### Latest degree

A Level or less

##### Other areas of specialty/work

General Practitioner

##### Street address

No. 10, Olfat Alley, Omid Ave, North Montazeri Ave

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Najafabad

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##### Postal code

8514958161

##### Phone

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##### Email

Alizamanian9674@gmail.com

## Person responsible for scientific inquiries

#### Contact

##### Name of organization / entity

Kashan University of Medical Sciences

##### Full name of responsible person

Dr. Hamed Pahlavani

##### Position

Assistant Professor

##### Latest degree

Specialist

##### Other areas of specialty/work

Anesthesiology

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## Person responsible for updating data

### Contact

**Name of organization / entity**  
Kashan University of Medical Sciences  
**Full name of responsible person**  
Ali Zamanian Najafabadi  
**Position**  
Student  
**Latest degree**  
A Level or less  
**Other areas of specialty/work**  
General Practitioner  
**Street address**  
No. 10, Olfat Alley, Omid Ave, North Montazeri Ave  
**City**  
Najafabad  
**Province**  
Isfahan  
**Postal code**

8514958161  
**Phone**  
+98 31 4251 0991  
**Email**  
Alizamanian9674@gmail.com

## 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

There is no more information

### 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

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