Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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

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)

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+98 31 4251 0991

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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.

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
Isfehan

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
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Kashan Shahid Beheshti Hospital., Pezeshk Blvd., Qutb Rawandi Blvd., Kashan Town,. Isfahan,. Iran
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
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Full name of responsible person
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University of Medical Sciences., Pezeshk Blvd., Qutb Rawandi Blvd., Kashan Town,. Isfahan,. Iran
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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
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
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Latest degree

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Other areas of specialty/work

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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