Clinical Trial Protocol
Iranian Registry of Clinical Trials

13 Jun 2026

Comparison of prophylactic effect of ondansetron, dexamethasone, combination of these drugs and placebo on decreasing nausea and vomiting in children aged 1 to 12 years undergoing upper gastrointestinal endoscopy

Protocol summary

Study aim

Determination of preventive effect of Ondansetron, Dexamethasone, and combination of the two drugs on reduction of Nausea and Vomiting in children aged 1 to 12 years under upper gastrointestinal endoscopy and its comparison with the control group.

Design

This triple blind, randomized clinical trial with parallel group design consists of 146 children at the age of 1-12 years old who will undergo upper gastrointestinal endoscopy. They will randomly be divided into 4 36-member groups.

Settings and conduct

This study was conducted at Imam Hossein Hospital in Isfahan in 2016. The target population of the study was consisted of children aged 1 to 12 years who were candidates for endoscopy.

Participants/Inclusion and exclusion criteria

Inclusion criteria: children of 1 to 12 years of age, Endoscopy candidate, ASA class I, II; Parental consent. Exclusion criteria: Allergy to study drug; severe cardiovascular disease; severe pulmonary disease; uncontrolled diseases

Intervention groups

Intervention group 1: received 0.1 mg/kg of Ondansetron, Intervention group 2:0.2 mg/kg Dexamethasone, Intervention group 3: the combination of the two above mentioned drugs, Intervention group 4: Normal Saline (Placebo) was given with the same volume.

Main outcome variables

nausea and vomiting; Duration of stay in recovery; mean arterial blood pressure; heart rate; arterial oxygen saturation

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20160307026950N7**
Registration date: **2018-07-13, 1397/04/22**
Registration timing: **retrospective**

Last update: **2018-07-13, 1397/04/22**
Update count: **0**

Registration date

2018-07-13, 1397/04/22

Registrant information

Name

Behzad Nazemroaya

Name of organization / entity

Isfahan University of Medical Sciences

Country

Iran (Islamic Republic of)

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behzad_nazem@med.mui.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2016-01-21, 1394/11/01

Expected recruitment end date

2016-07-22, 1395/05/01

Actual recruitment start date

2016-07-21, 1395/04/31

Actual recruitment end date

2017-04-20, 1396/01/31

Trial completion date
empty

Scientific title
Comparison of prophylactic effect of ondansetron, dexamethasone, combination of these drugs and placebo on decreasing nausea and vomiting in children aged 1 to 12 years undergoing upper gastrointestinal endoscopy

Public title
The effects of ondansetron, dexamethasone and the combination of these two drugs in reducing nausea and vomiting in children

Purpose
Prevention

Inclusion/Exclusion criteria

Inclusion criteria:
Children aged 1 to 12 years old ASA I and II candidates for upper gastrointestinal tract endoscopy parental consent for participation in the study

Exclusion criteria:
History of allergy to study drug Severe respiratory disease Severe cardiovascular disease uncontrolled diseases

Age
From **1 year** old to **12 years** old

Gender
Both

Phase
3

Groups that have been masked

- Participant
- Care provider
- Outcome assessor
- Data analyser

Sample size
Target sample size: **144**
Actual sample size reached: **140**

Randomization (investigator's opinion)
Randomized

Randomization description
The convenience sampling was used for enrolment in this study. Patients were then randomly allocated to groups “A”, “B”,“C” and “D” using the sealed envelope to receive either ondansetron, dexamethasone, combination of the two drugs or placebo respectively.

Blinding (investigator's opinion)
Triple blinded

Blinding description
For blinding purpose, one of the anesthesiologists was responsible for patient randomization and induction of general anesthesia while another investigator who was unaware of group allocation was responsible for data collection. For the purpose of making the study double blind, patients were also kept unaware of group allocation.

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Isfahan University of Medical Sciences

Street address
Isfahan University of Medical Sciences, Hezar Jarib street, Azadi square, Isfahan

City
Isfahan

Province
Isfehan

Postal code
8174673461

Approval date
2015-05-27, 1394/03/06

Ethics committee reference number
IR.MUI.REC.1394.3.673

Health conditions studied

1

Description of health condition studied
nausea and vomiting

ICD-10 code
R11

ICD-10 code description
Nausea and vomiting

Primary outcomes

1

Description
Heart rate

Timepoint
Before the intervention (0), then every 5 minutes until the end of endoscopy and then every 15 minutes until discharge the recovery

Method of measurement
Pulse oximetry device

2

Description
nausea and vomiting

Timepoint
Every 15 minutes in recovery room, and then 2, 4 and 6 hours after endoscopy

Method of measurement
Baxter Retching Face Nausea Scale

3

Description
Mean arterial blood pressure
Timepoint
Before the intervention (0), then every 5 minutes until the end of endoscopy and then every 15 minutes until discharge the recovery
Method of measurement
non invasive blood pressure sphygmomanometer

4

Description
arterial oxygen saturation
Timepoint
Before the intervention (0), then every 5 minutes until the end of endoscopy and then every 15 minutes until discharge the recovery
Method of measurement
Pulse oximetry device

Secondary outcomes

1

Description
Duration of stay in recovery
Timepoint
From recovery admission to recovery discharge
Method of measurement
Watch or clock

Intervention groups

1

Description
The intervention group (o): First, informed consent is obtained from the child's parents. After placement of the patients on the bed and attaching standard monitoring devices including the pulse oximeter, capnography and ECG, the vital signs will be recorded and the medications will be administered bolus and then through infusion. In group (0), 0.1 mg/kg of ondansetron will be prescribed and the average arterial blood pressure and heart rate will be recorded at baseline, and then every 5 minutes until the end of the endoscopy process, at recovery admission and then every 15 minutes until the recovery discharge.
Category
Prevention

2

Description
The intervention group (d): First, informed consent is obtained from the child's parents. After placement of the patients on the bed and attaching standard monitoring devices including the pulse oximeter, capnography and ECG, the vital signs will be recorded and the medications will be administered bolus and then through infusion. In group (d), 0.2 mg/kg of dexamethasone will be prescribed and the average arterial blood pressure and heart rate will be recorded at baseline, and then every 5 minutes until the end of the endoscopy process, at recovery admission and then every 15 minutes until the recovery discharge.
Category
Prevention

3

Description
The intervention group (o+d): First, informed consent is obtained from the child's parents. After placement of the patients on the bed and attaching standard monitoring devices including the pulse oximeter, capnography and ECG, the vital signs will be recorded and the medications will be administered bolus and then through infusion. In group (o+d), 0.1 mg/kg of ondansetron and 0.2 mg/kg of dexamethasone will be prescribed and the average arterial blood pressure and heart rate will be recorded at baseline, and then every 5 minutes until the end of the endoscopy process, at recovery admission and then every 15 minutes until the recovery discharge.
Category
Prevention

4

Description
Control group (n): First, informed consent is obtained from the child's parents. After placement of the patients on the bed and attaching standard monitoring devices including the pulse oximeter, capnography and ECG, the vital signs will be recorded and the medications will be administered bolus and then through infusion. In group (n), 1 milliliter of normal saline will be prescribed and the average arterial blood pressure and heart rate will be recorded at baseline, and then every 5 minutes until the end of the endoscopy process, at recovery admission and then every 15 minutes until the recovery discharge.
Category
Placebo

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam Hossein hospital
Full name of responsible person
Amir Shafa
Street address
Emam Khomeini boulivard
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
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8174673461
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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
Esfahan 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
Esfahan University of Medical Sciences
Full name of responsible person
Fatemeh Jafari
Position
Medical student/ Intern
Latest degree
Medical doctor
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Person responsible for updating data

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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
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
Yes - There is a plan to make this available

Analytic Code
Not applicable

Data Dictionary
Not applicable

Title and more details about the data/document
Only registered symptoms can be shared without mentioning the names of the participants.

When the data will become available and for how long
Access period 8months after printing results

To whom data/document is available
Researchers working in academia and academia

Under which criteria data/document could be used
Requesting by e-mail

From where data/document is obtainable
The request is sent to the person via e-mail and will be answered after a review within 10 working days

What processes are involved for a request to access data/document
The request is reviewed by the Person responsible for general inquiries and will be answered within ten days after obtaining the consent of the Person responsible for scientific inquiries.

Comments