Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Jun 2026

Effectiveness of intravenous Dexamethasone on the incidence of nausea and vomiting after deep sedation, in upper GI endoscopy in pediatric patients

Protocol summary

Study aim

Determinig the effectiveness of intravenous Dexamethasone on the incidence of nausea and vomiting after deep sedation, in upper GI endoscopy in pediatric patients

Design

Randomized, parallel group trial with blinded outcome assessment and postoperative care.

Settings and conduct

Based on the inclusion and exclusion criteria, 98 children aged 2 to 14, candidate for an elective upper GI endoscopy are selected, and after an informed consent is obtained from their parents, are randomly divided into 2 groups. In both groups standard monitoring devices will be installed. after preoxigenation with 100% O2, anesthesia is induced with 2.5 mg/kg thiopental and deepened with Sevoflurane. Preopertively, in the intervention group 0/1 mg/kg IV Dexamethasone and in the control, same volume of IV normal saline will be administered. Postoperatively, data on incidence of Nausea/vomiting and other outcomes will be collected in the recovery room, by an investigator who is blinded to the intervention allocation.

Participants/Inclusion and exclusion criteria

Inclusion criteria: All 2 to 14 year-old children, who are a candidate for an elective upper GI endoscopy, and whose parents have given an informed consent; Exclusion criteria: Patients with a history of hypersensitivity to the drugs studied, metabolic disease or diabetes, anatomical upper airway disorders, Patients diagnosed with behavioral disorders or currently taking psychiatric medication, patients who have previously undergone chemotherapy or have taken a sedative/hypnotic drug prior to endoscopy, Patients who are a candidate for an emergency endoscopy or whose operation is complicated and takes too long to be completed

Intervention groups

For intervention group 0/1 mg/kg IV Dexamethasone, and for the control, same volume of IV normal saline will be administered before operation.

Main outcome variables

Incidence of nausea/vomiting after endoscopy

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20180929041173N1**
Registration date: **2018-10-26, 1397/08/04**
Registration timing: **prospective**

Last update: **2019-09-20, 1398/06/29**
Update count: **2**

Registration date

2018-10-26, 1397/08/04

Registrant information

Name

Hamed Moheimani

Name of organization / entity

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-11-03, 1397/08/12

Expected recruitment end date

2018-11-13, 1397/08/22

Actual recruitment start date
2018-11-03, 1397/08/12
Actual recruitment end date
2018-11-21, 1397/08/30
Trial completion date
2018-11-21, 1397/08/30

Scientific title
Effectiveness of intravenous Dexamethasone on the incidence of nausea and vomiting after deep sedation, in upper GI endoscopy in pediatric patients

Public title
Antiemetic effect of Dexamethasone in pediatric endosocopy
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
All 2 to 14 year-old children, candidate for an elective upper GI endoscopy, according to the pediatric gastroenterologist diagnosis
Exclusion criteria:
Patients with a history of hypersensitivity to the drugs studied Patients with a history of metabolic disease or diabetes Patients with anatomical upper airway disorders Patients diagnosed with behavioral disorders or currently taking psychiatric medication Patients with a history of undergoing chemotherapy Patients who have taken a sedative/hypnotic drug prior to endoscopy Patients who are a candidate for an emergency endoscopy Patients whose operation is complicated (e.g. by bleeding) and takes too long to be completed Patients without a parental informed consent
Age
From **2 years** old to **14 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **98**
Actual sample size reached: **98**
Randomization (investigator's opinion)
Randomized
Randomization description
A statistical computer program is used to make random block stratified individual assignments with user selected block sizes. The psuedonumber generator is a linear congruential algorithm of Park and Millller with Bays-Durham shuffling. The random sheets will be given directly to nurse administrating the drugs and neither the participants nor the researcher collecting the data will be informed of the method of drug allocation to patients.
Blinding (investigator's opinion)
Double blinded
Blinding description
The randomly allocated list of patients will be given exclusively to the nurse administrating the drugs. Participants, gastroenterologist performing endoscopy, attending anesthesiologist, recovery nurse and the researcher collecting data will not be informed of the method of drug allocation to patients. (The parents of participants will be thoroughly informed that this clinical trial uses a randomized method before giving consent)
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Tehran University of Medical Sciences
Street address
Central office of Tehran University of Medical sciences, on the corner of Qods st., Keshavarz Boulevard, Tehran, Iran. PC: 1417653761
City
Tehran
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Approval date
2018-10-17, 1397/07/25
Ethics committee reference number
IR.TUMS.MEDICINE.REC.1397.505

Health conditions studied

1

Description of health condition studied
Post endoscopy nausea and vomiting
ICD-10 code
R11
ICD-10 code description
Nausea and vomiting

Primary outcomes

1

Description
incidence of nausea/vomiting
Timepoint
Recording the incidence of nausea/vomiting, evaluated

during patients' stay in the post-anesthesia recovery room

Method of measurement

Investigator evaluation and examination

Secondary outcomes

1

Description

Post anesthesia emergence delirium

Timepoint

Recording the highest score of patients on PAED sacle, during their stay in the post-anesthesia recovery room

Method of measurement

Pediatric Anesthesia Emergence Delirium (PAED) Scale

2

Description

incidence of bronchospasm/laryngospasm

Timepoint

Recording the incidence bronchospasm/laryngospasm, evaluated during patients' stay in the post-anesthesia recovery room

Method of measurement

Investigator evaluation and examination

3

Description

Time needed for patient recovery after endoscopy

Timepoint

Recording the time of patients stay in the post-anesthesia recovery room after endoscopy

Method of measurement

Subtracting the recorded time of entry to the recovery room, from the time the patient is eligible for transfer to the secondary recovery facilities

4

Description

Patients recovery state

Timepoint

Patients score on the Modified Aldrete scale is calculated and recorded at the time of entry to post-anesthesia recovery room, 5 minutes after entry, and at the time of discharge

Method of measurement

Modified Aldrete scale

Intervention groups

1

Description

Intervention group: After anesthesia is induced and deepened, 0/1 mg/(kg of body weight) of Dexamethasone is administered to patients intravenously

Category

Treatment - Drugs

2

Description

Control group: After anesthesia is induced and deepened, same volume of normal saline is administered to patients intravenously

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Tehran Childrens Medcial Center hospital

Full name of responsible person

Hamed Moheimani

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Mohammad Ali Sahraian

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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

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Hamed Moheimani

Position

Medical doctor, researcher

Latest degree

Medical doctor

Other areas of specialty/work

Internal Medicine

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Latest degree

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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
Not applicable
Analytic Code
Not applicable
Data Dictionary
Not applicable

Trial results

Please tick if results have been published
Yes
Summary result posting date
2019-09-20, 1398/06/29
Table of baseline comparison
Participant flow diagram
Table of variable outcomes' results
Table of adverse events
First publication date
2019-09-01, 1398/06/10
Abstract of published paper
Objectives: We aimed to evaluate the effect of a single dose of preoperative dexamethasone on postoperative nausea and vomiting (PONV), a frequent complication and a major cause of delayed recovery in pediatric upper gastrointestinal endoscopy (UGIE) under sedation. Methods: In this double-blind randomized controlled study, 98 children aged 2 to 14, with American Society of Anesthesiologists status I to II, and undergoing elective UGIE with deep sedation were included and randomly assigned to 2 groups. Preoperatively, after anesthesia induction with sodium thiopental and maintenance with sevoflurane, patients in the intervention (n = 49) and control (n = 49) groups, respectively received 0.1 mg/kg i.v. dexamethasone and 2 cm3 i.v. 0.9% saline. Postoperatively, PONV incidence was measured as the primary outcome. Results: PONV incidence was significantly less in dexamethasone group (8.2%) compared to the control group (26.5%) (difference = 18.3%, 95% confidence interval: 3.4%−33%, P = 0.016). For secondary outcomes, between-group differences were not statistically significant: incidence of bronchospasm or laryngospasm (both 4.1%, P = 1); emergence delirium assessed with Pediatric Anesthesia Emergence Delirium scale (5.9 ± 3.4 vs 5.7 ± 3.2, P = 0.751); Modified Aldrete score at 0 minutes (9.4 ± 0.8 vs 9.3 ± 0.9, P = 0.909) and at 5 minutes (9.5 ± 0.7 vs 9.4 ± 0.9, P = 0.527); and recovery time (21.1 ± 6.6 vs 23.4 ± 8.6 minutes, P = 0.130). Conclusions: A single preoperative dose of i.v. dexamethasone reduces PONV in children undergoing elective UGIE with deep sedation, but has no significant effect on the patient recovery time or the incidence of postoperative bronchospasm or laryngospasm and emergence delirium.