Clinical Trial Protocol
Iranian Registry of Clinical Trials

27 May 2026

Comparison of the effect of Dexamethasone and Ondansetron on nausea,vomiting and delirium in children undergoing upper GI endoscopy

Protocol summary

Study aim
Comparison of the effect of administering injectable dexamethasone with injectable ondansetron before upper endoscopy in reducing of PONV and Delirium in Children referred to Kashan Shahid Beheshti Hospital and Isfahan Imam Hossein Children's Hospital 2020

Design
Clinical trial with control group, with parallel groups, single blind, randomized, phase three on 60 patients (20 people in each of the three groups). For randomization from the website www. sealedenvelope.com/simple-randomiser/v1/lists was used.

Settings and conduct
This study is a single- blind clinical trial (participants did not know how to do the work) on upper endoscopic candidate children referred to Beheshti Hospital in Kashan and Imam Hossein in Isfahan, After receiving informed written consent from their parents. Patients are randomly allocated into dexamethasone, ondansetron and control groups. All patients undergo a pre-determined and uniform procedure and will undergo standard venipuncture and monitoring. To maintain anesthesia, an endoscopic mask with an endoscope passage and no leakage will be used at the same time as the endoscopy. Anesthesia is performed with midazolam and then propofol under the supervision of an anesthesiologist. Prior to UGIE, one group received 0.1 mg / kg intravenous dexamethasone, the other group received 0.15 mg / kg intravenous ondansetron, and the control group did not receive any medication.

Participants/Inclusion and exclusion criteria
Children 5 to 14 years of age, diagnosed by a gastroenterologist, are candidates for elective UGIE under deep anesthesia.

Intervention groups
In the two intervention groups, when the patient was sufficiently anesthetized, one group received dexamethasone 0.1 mg / kg and the other group, ondansetron 0.15 mg / kg, was not given the control group.

Main outcome variables
PONV, Delirium

General information

Reason for update
Over the past year, the presence of coronavirus pandemics and specific conditions in the country and consecutive closures have led to a significant reduction in referrals (elective patients) to the hospital and endoscopy unit. Due to this, the process of collecting samples has become very slow Considering that the estimated number of samples is 90 people and so far we have managed to collect 60 samples after 9 months, we need to adjust the number of samples. Note that my residency ended 7 months ago.

Acronym

IRCT registration information
IRCT registration number: **IRCT20200809048343N1**
Registration date: **2020-11-13, 1399/08/23**
Registration timing: **registered_while_recruiting**

Last update: **2021-04-28, 1400/02/08**
Update count: **1**

Registration date
2020-11-13, 1399/08/23

Registrant information
Name
Mahsa Nassaj
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 31 5534 0342
Email address
mahsa.nassaj87@gmail.com

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2020-08-22, 1399/06/01
Expected recruitment end date
2021-02-18, 1399/11/30
Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Comparison of the effect of Dexamethasone and Ondansetron on nausea,vomiting and delirium in children undergoing upper GI endoscopy

Public title
Comparison of the effect of Dexamethasone and Ondansetron on nausea , vomiting and delirium in children undergoing upper GI endoscopy
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:
Children 5 to 14 years old who are candidates for UGIE with deep anesthesia ASA stage : 1 , 2 Modified APFEL score 0 , 1
Exclusion criteria:
History of allergies to the drugs used in the study History of previous chemotherapy History of malignancy History of metabolic disease History of diabet Upper respiratory tract anatomical disease Treatment with Psychiatric drugs/Behavioural disorder Children who have received sedatives before the procedure. Children who are candidates for ERCP or emergency endoscopy Children who receive higher doses of the drug due to the difficulty of the operation to prolong the duration of anesthesia
Age
From **5 years** old to **14 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant

Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
First, the group receiving dexamethasone was coded with the letter A, the group receiving ondansetron with the letter B and the control group with the letter C, and then using the website www. sealedenvelope.com/simple-randomiser/v1/lists Randomization list was prepared by selecting a sample size of 60 (three groups of 30) and Permuted block randomization method (block size=6) (10 blocks of 6). Then, through the obtained randomization list, the subjects will be assigned to one of the three groups A or B or C. For example, suppose that in the first six blocks, the permutation method is AABCBC, so the first and second samples are group A (dexamethasone), the third and fifth samples are group B (ondansetron), and the fourth and sixth samples are Group C (control) will be assigned and the same will continue until the last sample (60th person).
Blinding (investigator's opinion)
Single blinded
Blinding description
In this study, participants did not know how to work and prescribe drugs.
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 Science
Street address
3 km of Ravand road, Physician Boulevard., Medical School
City
Kashan
Province
Isfehan
Postal code
8715988141
Approval date
2020-07-13, 1399/04/23
Ethics committee reference number
IR.KAUMS.MEDNT.REC.1399.053

Health conditions studied

1

Description of health condition studied
dyspepsia
ICD-10 code
R10.1
ICD-10 code description
Dyspepsia NOS /Epigastric pain

Primary outcomes

1

Description
Percentage of people with nausea and vomiting

Timepoint
Existence of nausea-vomiting after the intervention
Method of measurement
view

2

Description
Intensity of delirium in individuals
Timepoint
Measurement of delirium severity after intervention (during recovery)
Method of measurement
PAED Scaling Score

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group: In the dexamethasone group, 0.1 mg / kg dexamethasone is injected when the anesthesia level is sufficient.
Category
Prevention

2

Description
Intervention group: In the ondansetron group, 0.15 mg / kg of ondansetron is injected when the anesthesia level is sufficient.
Category
Prevention

3

Description
Control group: In the control group, no drug is injected.
Category
Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Esfahan Imam Hossein Hospital
Full name of responsible person
Dr.Sedigheh Shahhosseini
Street address
Imam Khomeini St., before Esteghlal Square, Imam Hossein Educational and Medical Center
City
Esfahan
Province
Isfehan
Postal code
8195163381
Phone
+98 31 3386 6266
Fax
+98 31 3386 8286
Email
emamhossein_hospital@mui.ac.ir

2

Recruitment center
Name of recruitment center
Kashan Shahid Beheshti Hospital
Full name of responsible person
Dr.Ramin Madani ,Dr. Mahsa Nassaj
Street address
Qutb Ravandi Boulevard
City
Kashan
Province
Isfehan
Postal code
87159/81151
Phone
+98 31 5554 0026
Fax
+98 31 5554 8900
Email
beheshtihospital@kaums.ac.ir
Web page address

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Kashan University of Medical Sciences
Full name of responsible person
Dr. Hamidreza Banafsheh
Street address
Qutb Ravandi Boulevard
City
Kashan
Province
Isfehan
Postal code
8115187159
Phone
+98 31 5557 8010
Email
education@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
50
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

Dr.Mahsa Nassaj

Position

Specialist

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

Street address

Amir Kabir Street

City

Kashan

Province

Isfehan

Postal code

8718646351

Phone

+98 31 5534 0342

Email

mahsa.nassaj87@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr.Ramin Madani

Position

Assistant Professor

Latest degree

Subspecialist

Other areas of specialty/work

Pediatrics

Street address

Qutb Ravandi Boulevard

City

Kashan

Province

Isfehan

Postal code

8115187159

Phone

+98 31 5531 7889

Email

drraminmadani@gmail.com

Person responsible for updating data

Contact

Name of organization / entity

Kashan University of Medical Sciences

Full name of responsible person

Dr.Mahsa Nassaj

Position

Specialist

Latest degree

Specialist

Other areas of specialty/work

Pediatrics

Street address

Amirkabir Street

City

Kashan

Province

Isfehan

Postal code

8718646351

Phone

+98 31 5534 0342

Email

mahsa.nassaj87@gmail.com

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

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Its release schedule is not yet known

When the data will become available and for how long

Its release schedule is not yet known

To whom data/document is available

Its release schedule is not yet known

Under which criteria data/document could be used

Its release schedule is not yet known

From where data/document is obtainable

Its release schedule is not yet known

What processes are involved for a request to access data/document

Its release schedule is not yet known

Comments