

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 diabetes 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

Isfahan

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

Isfahan

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

Isfahan

Postal code

87159/81151

Phone

+98 31 5554 0026

Fax

+98 31 5554 8900

Email

beheshthospital@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

Isfahan

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
Isfahan
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
Isfahan
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
Isfahan
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