Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of Metoclopramide and Dexamethasone versus Metoclopramide itself in the control of vomiting due to minor head trauma in the age range of 2-8 years old

Protocol summary

Summary

Goal: Comparison of Metoclopramide and Dexamethasone versus Metoclopramide alone in the control of vomiting due to minor head trauma in the children age range of 2-8 years old. Inclusion criteria: Patients with GCS 14-15; minor trauma associated with vomiting and normal CT. Exclusion criteria: unstable hemodynamics; neurological disorders; restless leg syndrome; the use of antiemetic medications during past 8 hours; recent receipt of injectable drugs; Nausea and vomiting caused by motion sickness; chemotherapy and radiotherapy; having contraindications for dexamethasone; simultaneous treatment with corticosteroids; diarrhea and a child who is under treatment with sedative drugs. This study will be done as a double-blind randomized controlled trial. We will recruit 60 patients, which has nausea and vomiting followed by minor head trauma, which were referred to the hospital. Twenty minutes before intervention, consciousness of patients and the severity of vomiting, will be recorded based on Visual Analog Scale. This test is a criterion for measuring the intensity of vomiting. A group of patients will receive 0.15 mg/kg Intramuscular injection of Metoclopramide and 0.15 mg/kg intramuscular Dexamethasone; and the other group will receive 0.15 mg/kg intramuscular Metoclopramide and 0.15 mg/kg intramuscular distilled water (placebo). Then, after 20, 40 and 60 minutes, and then every hour up to four hours after intervention the vital signs including (respiratory rate, heart rate,...) and their level of consciousness and also the variations and severity of vomiting will be recorded and will be checked by phone call. Finally, the differences between the two groups will be examined.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016081128944N1**
Registration date: **2016-08-11, 1395/05/21**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2016-08-11, 1395/05/21

Registrant information

Name

Seyed Mohammad Kazem Mortazavi

Name of organization / entity

Ahvaz Jundishapur University Of Medical Sciences.

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapur University Of Medical Sciences, Ahvaz, Iran

Expected recruitment start date

2016-07-26, 1395/05/05

Expected recruitment end date

2016-12-25, 1395/10/05

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title
Comparison of Metoclopramide and Dexamethasone versus Metoclopramide itself in the control of vomiting due to minor head trauma in the age range of 2-8 years old

Public title
Compare the efficacy of Metoclopramide and Dexamethasone with Metoclopramide itself in the control of vomiting due to mild head trauma in children between the ages of 8-2 years

Purpose
Treatment

Inclusion/Exclusion criteria
Inclusion criteria: Patients with GCS 14-15; aged between 2-8 years; minor trauma associated with vomiting and normal CT. Exclusion criteria: unstable hemodynamics; neurological disorders; restless leg syndrome; the use of antiemetic medications during past 8 hours; recent receipt of injectable drugs; Nausea and vomiting caused by motion sickness; chemotherapy and radiotherapy; allergy to metoclopramide or dexamethasone; having contraindications for dexamethasone; simultaneous treatment with corticosteroids; diarrhea and a child who is under treatment with sedative drugs.

Age
From **2 years** old to **6 years** old

Gender
Both

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **60**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ahvaz Jundishapur University Of Medical Sciences, Ahvaz, Iran

Street address
Ahvaz Jundishapur University Of Medical Sciences, Golestan Ave.

City
Ahvaz

Postal code

Approval date
2016-06-14, 1395/03/25

Ethics committee reference number
IR.AJUMS.REC.1395.188

Health conditions studied

1

Description of health condition studied
vomiting caused by minor head trauma

ICD-10 code
F50.5

ICD-10 code description
Vomiting associated with other psychological disturbances

Primary outcomes

1

Description
vomiting caused by minor head trauma

Timepoint
20 minutes before the Intervention

Method of measurement
VAS test

Secondary outcomes

1

Description
vital signs (respiratory rate, heart rate) and their alertness

Timepoint
after 20,40 and 60 minutes, and also hourly (until 4 hours after the intervention of patients' vital signs)

Method of measurement
Pulse Oximeter, manometer, counting the respiratory rate

Intervention groups

1

Description
The intervention group In this study, one group of patients will receive 0.15mg/kg Metoclopramide and also 0.15 mg/kg Dexamethazone intramuscularly. Then, after 20,40 and 60 minutes, and also each hour (until 4 hours after the intervention) the patients' vital signs including (blood pressure, respiratory rate, heart rate, blood oxygen concentration), the consciousness level of patients and vomiting intensity changes will be measured and recorded. If the patient is discharged from the hospital, he/she will receive a phone call for follow for up to 24 hours. Finally, the differences in these

parameters between the two groups will be examined. If the both groups will not respond to the therapeutic intervention or they have deterioration in general condition, other lines of treatment or repetition of the intervention should be considered. If it will happen before the first 20 minutes after intervention, she/he will be excluded. The data from the assessment will be analyzed by SPSS software version 22.

Category

Treatment - Drugs

2

Description

Control group: In this study, this group will receive 0.15mg/kg Metoclopramide and also, 0.15mg/kg distilled water (Placebo) intramuscular. Then, after 20, 40 and 60 minutes, and also each hour (until 4 hours after intervention) the vital signs of patients including (blood pressure, respiratory rate, heart rate, blood oxygen concentration) , the consciousness of patients and vomiting intensity changes will be measured and recorded. If the patient is discharged from the hospital, he/she will have a telephone call for follow up until 24 hours. Finally, the differences in these parameters between the two groups will be examined. If the both groups had not an appropriate response to the therapeutic intervention, and if their general condition will be deteriorate, other lines of treatment or repetition of the intervention will be done. If patients need other treatment before 20 minute, they will be excluded from the study. The data from the assessment will be analyzed by SPSS software version 22.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Golestan Hospital

Full name of responsible person

Seyed Mohammad Kazem Mortazavi

Street address

Golestan Hospital, Golestan Ave

City

Ahvaz

2

Recruitment center

Name of recruitment center

Imam Khomeini Hospital

Full name of responsible person

Seyed Mohammad Kazem Mortazavi

Street address

Imam Khomeini Hospital, Sharifzadeh st. Azadegan Ave.

City

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahvaz Jundishapur University Of Medical Sciences, Ahvaz, Iran

Full name of responsible person

Mr. Dianat

Street address

Ahvaz Jundishapur University Of Medical Sciences, Golestan Ave.

City

Ahvaz

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Ahvaz Jundishapur University Of Medical Sciences, Ahvaz, Iran

Proportion provided by this source

100

Public or private sector

empty

Domestic or foreign origin

empty

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

empty

Person responsible for general inquiries

Contact

Name of organization / entity

Ahvaz Jundishapur University Of Medical Sciences, Ahvaz, Iran

Full name of responsible person

Mahdis vakili

Position

Nutritionist

Other areas of specialty/work

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty

Study Protocol
empty

Statistical Analysis Plan
empty

Informed Consent Form
empty

Clinical Study Report
empty

Analytic Code
empty

Data Dictionary
empty