Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparing the preventive effect of variuos combinations of ondansetron,dexamethason and metoclopramide on post operative nausea and vomiting after balanced anesthesia for orthopedic surgery

Protocol summary

Summary

The aim of this study is comparing the effectiveness of Dexamethason,Metclopramide and Ondansetron alone and in various 1-1 combinations. 420 patients age 16-65 ,American Society of Anesthesiologists Physical Status 1-2 ,with no important known organ disease who are candidate for orthopedic surgery under general anesthesia would be included.Patients would allocated into 6 intervention and 1 control groups randomly as following: intervention group 1:ondansetron 4mg=4cc =Intravenous intervention group 2:metoclopramid 4mg=4cc=Intravenous intervention group 3:dexamethason 4mg=4cc =Intravenous intervention group 4:ondansetron 4mg+metoclopramid 4mg=4cc=Intravenous intervention group 5: ondansetron 4mg+dexamethason 4mg=4c=Intravenousc intervention group 6: metoclopramid 4mg+dexamethason4mg=4cc=Intravenous Goup 7=Control group :placebo =normal saline =4cc =Intravenous Study drugs (single or 1-1 combinations) or placebo (4 cc normal saline) will be administered when the surgeon begin suturing the fascia . Occurrence of nausea and vomiting will be measured by Post Operative Nausea and Vomiting (PONV) score at the end of recovery stay and 2 hours after transferring the patient to the ward and every 8 hours thereafter for the next 24 hours.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201108067093N2**
Registration date: **2012-09-26, 1391/07/05**
Registration timing: **registered_while_recruiting**
Last update:
Update count: **0**

Registration date

2012-09-26, 1391/07/05

Registrant information

Name
Mohsen Saber Moghadamranjbar
Name of organization / entity
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Recruitment status

Recruitment complete

Funding source

North khorasan University Of Medical Science- Deputy Of Research And Technology

Expected recruitment start date

2012-05-21, 1391/03/01

Expected recruitment end date

2012-11-20, 1391/08/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparing the preventive effect of variuos combinations of ondansetron,dexamethason and metoclopramide on post operative nausea and vomiting after balanced anesthesia for orthopedic surgery

Public title
comparison of various combinations of ondansetron ,dexamethson and methoclopramide for prevention of post operative nausea and vomiting
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:ASA class 1,2; age 16-65;BMI<30; Candidate for orthopedic surgery Exclusion criteria:Severe sleep apnea syndrome;Significant cardiac,respiratory,hepatic,gastrointestinal or renal disease;Known hypersensitivity to each of study drug;History of post operative nausea and vomiting in previous surgeries;Taking medication with known antivomiting properties; Pregnant or breast feeding mother; Opioid and alcohol addiction;Difficult intubation
Age
From **16 years** old to **65 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **420**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Other
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Comittee Of North Khorasan University Of Medical Sciences
Street address
Deputy Of Research And Technology, Berenji Line, South Shariati,Bojnurd, Iran
City
Bojnurd
Postal code
Approval date
2012-04-29, 1391/02/10
Ethics committee reference number
90/60/06

Health conditions studied

1

Description of health condition studied
post operative nausea and vomiting
ICD-10 code
Y42.0
ICD-10 code description
Glucocorticoids and synthetic analogues

2

Description of health condition studied
post operatve nausea and vomiting
ICD-10 code
Y43.0
ICD-10 code description
Antiallergic and antiemetic drugs

Primary outcomes

1

Description
post operative nausea and vomiting
Timepoint
every 8 hours :first measurement:2 hours after discharge from recovery room and every 8 hours thereafter for the next 24 hours
Method of measurement
ponv scale

Secondary outcomes

1

Description
biochemical laboratory data
Timepoint
once (preoperative)
Method of measurement
blood test

Intervention groups

1

Description
intervention group 1:ondansetron 4mg=4cc,intravenous as stat injection
Category
Treatment - Drugs

2

Description
Control :placebo =normal saline =4cc ,intravenous as stat injectin
Category
Placebo

3

Description
intervention group 2:metoclopramid 4mg=4cc,intravenous as stat injectin
Category
Treatment - Drugs

4

Description
intervention group 3:dexamethason 4mg=4cc,intravenous as stat injectin
Category
Treatment - Drugs

5

Description
intervention group 4:ondansetron 4mg+metoclopramid 4mg=4cc ,intravenous as stat injectin
Category
Treatment - Drugs

6

Description
intervention group 5: ondansetron 4mg+dexamethason 4mg=4cc,intravenous as stat injectin
Category
Treatment - Drugs

7

Description
intervention group 6: metoclopramid 4mg+dexamethason4mg=4cc,intravenous as stat injectin
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Imam Ali Hospital
Full name of responsible person
Dr Sabermoghadam
Street address
Imam Ali Hospital, Shahriar Street -
City
Bojnurd

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
North Khorasan University Of Medical Sciences
Full name of responsible person
Saber Raeghi
Street address
Berenji Line, South Shariati
City
Bojnurd
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
North Khorasan University Of Medical Sciences
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
North Khorasan University of Medical Sciences, Bojnurd, Iran
Full name of responsible person
Dr Sabermoghadam
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Person responsible for scientific inquiries

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North Khorasan University of Medical Sciences, Bojnurd, Iran
Full name of responsible person
Dr Sabermoghadam,
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Fax

Email

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Web page address

Person responsible for updating data

Contact

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