

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jul 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, Metoclopramide 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

North khorasan University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 58 4229 7069

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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 antiemetic 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 Committee 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 operative 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

Position

Assistant Professor

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

Name of organization / entity

North Khorasan University of Medical Sciences,
Bojnurd, Iran

Full name of responsible person

Dr Sabermoghadam,

Position

Assistant Professor

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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