Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 2026

The effect of intravenous infusion and subcutaneous infiltration of metoclopramide on postoperative pain and nausea in lower abdominal surgery comparison with control group

Protocol summary

Study aim
Determining the effect of intravenous infusion and subcutaneous infiltration of metoclopramide on postoperative pain and nausea in lower abdominal surgery comparison with control group

Design
Clinical trial with control group, with parallel groups, randomized

Settings and conduct
The study was conducted in 1396-1397 in Al-Zahra hospital, Isfahan. The target population are the patients who referred to Al-Zahra hospital for elective lower abdominal surgery

Participants/Inclusion and exclusion criteria
Inclusion criteria: Patient aged 18-65 year referred to Al-Zahra hospital during the year 1396-1397 for elective lower abdominal surgery and classified as ASA physical status 1 & 2 were included Exclusion criteria: pregnancy, addiction to cigarette, opioid and alcohol, weight over 100 kg, allergy to metoclopramide, chronic pain that lasts more than 6 months, anxiety before surgery, taking any analgesic 24 hours before surgery

Intervention groups
The clinical trial study was performed on 75 patients undergoing lower abdominal surgery at Al-Zahra Medical center, Isfahan, Iran in 2015-17. Patients were randomly divided into three groups of intravenous, subcutaneous metoclopramide and control groups. Intensity of pain and nausea and hemodynamic parameters use were compared in three groups

Main outcome variables
Intensity of pain and nausea, hemodynamic parameters

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20190825044609N1**
Registration date: **2019-09-14, 1398/06/23**
Registration timing: **retrospective**

Last update: **2019-09-14, 1398/06/23**
Update count: **0**

Registration date
2019-09-14, 1398/06/23

Registrant information

Name
Fatemeh Panahi

Name of organization / entity

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Iran (Islamic Republic of)

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Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-04-21, 1396/02/01

Expected recruitment end date
2018-09-22, 1397/06/31

Actual recruitment start date
2017-08-23, 1396/06/01

Actual recruitment end date
2018-12-03, 1397/09/12

Trial completion date
2018-12-03, 1397/09/12

Scientific title
The effect of intravenous infusion and subcutaneous infiltration of metoclopramide on postoperative pain and

nausea in lower abdominal surgery comparison with control group

Public title
The effect of metoclopramide on postoperative pain and nausea
Purpose
Treatment
Inclusion/Exclusion criteria
Inclusion criteria:
Patients aged 18-65 year referred to Al-Zahra hospital during the year 1396-1397 for elective lower abdominal surgery and classified as ASA physical status 1 & 2 were included
Exclusion criteria:
Pregnancy Addiction to cigarette, opioid and alcohol Weight over 100 kg Allergy to metoclopramide Chronic pain that lasts more than 6 months Anxiety before surgery Taking any analgesic 24 hours before surgery
Age
From **18 years** old to **65 years** old
Gender
Both

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor
- Data analyser

Sample size
Target sample size: **75**
Actual sample size reached: **75**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization method: simple randomization Randomization unit: individual Randomization layer not done Randomization tool: random number table Who to create random sequence: Classification in groups like this: group A: 1-25 group B: 26-50 group C: 51-75 Allocation concealment: using numbered drug containers
Blinding (investigator's opinion)
Double blinded
Blinding description
A person who inject drugs is different from person who collect data
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Comitee of Isfahan University of Medical Science
Street address
Isfahan University of Medical Science,Hezar Jarib Sreet, Isfahan, Iran
City
Isfahan
Province
Isfehan
Postal code
8174675731
Approval date
2018-01-03, 1396/10/13
Ethics committee reference number
IR.MUI.MED.REC.1397.119

Health conditions studied

1

Description of health condition studied
Postoperative pain
ICD-10 code
ICD-10 code description

2

Description of health condition studied
Postoperative nausea
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Intensity of postoperative pain
Timepoint
In extubation time, 15 minutes, 30 minutes, 60 minutes, 2 hours, 4 hours, 8 hours, 16 hours, 24 hours after surgery
Method of measurement
Questionnaire according to Visual Analogue Scale

2

Description
Intensity of postoperative nausea
Timepoint
In extubation time, 15 minutes, 30 minutes, 60 minutes, 2 hours, 4 hours, 8 hours, 16 hours, 24 hours after surgery
Method of measurement
Questionnaire according to Visual Analogue Scale

Secondary outcomes

1

Description
Blood pressure
Timepoint
In extubation time, 15 minutes, 30 minutes, 60 minutes, 2 hours, 4 hours, 8 hours, 16 hours, 24 hours after surgery
Method of measurement
manometer

2

Description
Heart rate
Timepoint
In extubation time, 15 minutes, 30 minutes, 60 minutes, 2 hours, 4 hours, 8 hours, 16 hours, 24 hours after surgery
Method of measurement
pulseoxymeter

Intervention groups

1

Description
Intervention group 1: Intravenous injection of 0.15mg/kg metoclopramide in 5 cc normal saline and subcutaneous injection of 5cc normal saline
Category
Treatment - Drugs

2

Description
Intervention group 2: Subcutaneous injection of 0.15mg/kg metoclopramide in 5 cc normal saline and intravenous injection of 5cc normal saline
Category
Treatment - Drugs

3

Description
Control group: Subcutaneous injection of 5 cc normal saline and intravenous injection of 5cc normal saline
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Al-Zahra Medical Center, Isfahan
Full name of responsible person
Hamid Haji Gholam Saryazdi
Street address
Isfahan University of Medical Science -Hezar jarib street-Isfahan-Iran
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haji@med.mui.ac.ir

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Esfahan University of Medical Sciences
Full name of responsible person
Shaghayegh Haghjoo
Street address
Isfahan University of Medical Science, Hezar jarib street, Isfahan, Iran
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Email
haghjoo@med.mui.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Esfahan University of Medical Sciences
Proportion provided by this source
100
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
Esfahan University of Medical Sciences
Full name of responsible person
Hamid Haji Gholam Saryazdi
Position

Associate professor
Latest degree
Specialist
Other areas of specialty/work
Anesthesiology
Street address
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
Yes - There is 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
Whole data will be available
When the data will become available and for how long
Immediately after publishing manuscript
To whom data/document is available
To whom is in need to this data
Under which criteria data/document could be used
Email to Dr Hamid Haji Gholam Saryazdi email: haji@med.mui.ac.ir
From where data/document is obtainable
Dr Hamid Haji Gholam Saryazdi
What processes are involved for a request to access data/document
Email to Dr Hamid Haji Gholam Saryazdi email: haji@med.mui.ac.ir
Comments