

Clinical Trial Protocol

Iranian Registry of Clinical Trials

30 May 2026

Title: Comparing The Effect Of Ketorolac and Morphine With Morphine Alone in Postoperative Pain Management of Obese Patient Undergoing Gastric Bypass Surgery.

Protocol summary

Study aim

1- Determination of effect of Ketorolac and Morphine with Morphine alone in number needed to treat in postoperative pain management of obese patient undergoing gastric bypass surgery in Iranmehr hospital in 1396 2-Determination of effect of Ketorolac and Morphine with Morphine alone in pain score of 6th hour after surgery of obese patient undergoing gastric bypass surgery in Iranmehr hospital in 1396

Design

Sample size was 34 in each group due to Repeated Measure method (6 repeat) with G-Power statistical software. Type 1 error and statistical power was 0.05 and 95%. Participants are allocated in two groups by permuted block randomization method. Also Allocation concealment will be ensured, by assigning 5 digit code to participants in each group by a person who is not aware of hypothesis. Surgical and anesthetic plan was the same for two groups. Control group received patient control analgesia (PCA) with infusion of 0.8 mg morphine sulfate per hour and intervention group received PCA with infusion of 0.4 mg morphine sulfate plus 30 mg IV and 30 mg IM ketorolac and also 15 mg ketorolac IM each 6 hour. Pain in both group was evaluated by Visual Analogue Scale (VAS). At the time of entering ward, and 6, 12 and 24 hour after admission to ward VAS was measured. Dose of Acetaminophen and ondansetron used for each group also recorded.

Settings and conduct

This study was conducted in Iranmehr Hospital under supervision of anesthesiologist. In this study, due to intramuscular injection of ketorolac, participants and nurses in the operating room are not blinded. On the other hand data collector and outcome assessors will be blinded to the group of participants.

Participants/Inclusion and exclusion criteria

Inclusion Criteria BMI>40 BMI>35 with complications

ASA I & II Exclusion Criteria ASA >III Any changes in anesthesia or surgical plan Any history of addiction or substance abuse Any history of allergic reaction to drugs using in the study

Intervention groups

Control group received patient control analgesia (PCA) with infusion of 0.8 mg morphine sulfate per hour and intervention group received PCA with infusion of 0.4 mg morphine sulfate plus 30 mg IV and 30 mg IM ketorolac and also 15 mg ketorolac IM each 6 hour. Both of them in addition to the described regiment, will receive 1 gr of acetaminophen intravascular each 12 hour.

Main outcome variables

Pain score by VAS score Number needed to treat

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20171014036769N2**

Registration date: **2018-02-20, 1396/12/01**

Registration timing: **registered_while_recruiting**

Last update: **2018-02-20, 1396/12/01**

Update count: **0**

Registration date

2018-02-20, 1396/12/01

Registrant information

Name

Soodeh Tabashi

Name of organization / entity

Shahid Beheshti Medical University

Country

Iran (Islamic Republic of)

Phone

+98 21 8872 8251

Email address

Recruitment status

Recruitment complete

Funding source

Shahid Beheshti Medical University

Expected recruitment start date

2017-12-22, 1396/10/01

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Title: Comparing The Effect Of Ketorolac and Morphine With Morphine Alone in Postoperative Pain Management of Obese Patient Undergoing Gastric Bypass Surgery.

Public title

Postoperative Pain Management of Obese Patient Undergoing Gastric Bypass Surgery.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:

Body Mass Index >40kg/m² candidate for gastric bypass surgery
Body mass Index > 35kg/m² in addition to coexisting diseases such as diabetes, hypertension, renal disease, cardiovascular diseases
ASA class : 1 or 2

Exclusion criteria:

reported Addiction to psychotropic drugs or substance abuse
History of allergic reactions to drugs used in the study

Age

No age limit

Gender

Both

Phase

N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size

Target sample size: 72

Randomization (investigator's opinion)

Randomized

Randomization description

Participants are allocated in two groups by permuted block randomization method which the block size was assumed four. Also Allocation concealment will be ensured, by central telephone method and assigning 5 digit code to participants in each group by a person who is not aware of hypothesis.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, nurses in the operating room are not blinded. On the other hand data collector and outcome assessors will be blinded to the group of participants. Patient is blind to the group they are in.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of faculty of medicine, Shahid Beheshti Medical University

Street address

Shahid Beheshti University of medical sciences, Shahid Aarabi st., Yaman Ave., Shahid Chamran Highway, Tehran

City

Tehran

Province

Tehran

Postal code

19839-63113

Approval date

2017-02-14, 1395/11/26

Ethics committee reference number

IR.SBMU.MSP.REC.1395.541

Health conditions studied

1

Description of health condition studied

Post Operative Pain

ICD-10 code

G89.18

ICD-10 code description

Other acute postprocedural pain

2

Description of health condition studied

Morbid Obesity

ICD-10 code

E66

ICD-10 code description

Overweight and obesity

Primary outcomes

1

Description

VAS (Visual Analogue Scale) pain score

Timepoint

Immediately after the surgery, 6, 12, 24 hours later and at the time of discharge

Method of measurement

Pain score questionnaire

Secondary outcomes

1

Description

Post Operative Nausea and Vomiting

Timepoint

0,6,12,24 hours after exiting recovery room

Method of measurement

questionnaire

2

Description

Length of Stay

Timepoint

at the time of discharge

Method of measurement

questionnaire

Intervention groups

1

Description

Intervention group: patients will receive PCA infusion of 0.4 mg morphine sulfate per hour and Apotel 1 gram intravenously every 12 hours plus 30 mg IV and 30 mg IM ketorolac and also 15 mg ketorolac IV every 6 hours. If VAS score is more than 49mm patient will receive Apotel 1 gram intravenous with maximum dose of 4 gram daily. If the patient feel nausea, 4 mg intravenous Ondansetron will be administered.

Category

Treatment - Drugs

2

Description

Control group: patients in control group will receive patient control analgesia (PCA) with infusion of 0.8 mg morphine sulfate per hour and Apotel 1 gram intravenous each 12 hours at the time they discharge from the recovery ward. If VAS score is more than 49mm patient will receive Apotel 1 gram intravenous with maximum dose of 4 gram daily. If the patient feel nauseated, 4 mg intravenous Ondansetron will be administered.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Iran Mehr Hospital

Full name of responsible person

Dr Noor Mohammad Arefian

Street address

Gholhak, Shariati Ave. , Tehran

City

Tehran

Province

Tehran

Postal code

1949913413

Phone

+98 21 2200 9071

Email

soodeh.tabashi@yahoo.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shahid Beheshti Medical University

Full name of responsible person

Dr Noor Mohammad Arefian

Street address

Erabi St., Yaman St., Chamran Highway

City

Tehran

Province

Tehran

Postal code

1985717443

Email

info@sbmu.ac.ir

Web page address

<http://msp.sbmu.ac.ir/>

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shahid Beheshti Medical University

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

Shahid Beheshti Medical University

Full name of responsible person

Dr Soodeh Tabashi

Position

Resident of Anesthesiology

Latest degree

Medical doctor

Other areas of specialty/work**Street address**

Erabi St., Yaman St., Chamran Highway

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 2387 2592

Fax**Email**

school.of.medicine@sbm.u.ac.ir

Web page address

narefian@yahoo.com

Web page address

Person responsible for updating data

Contact

Name of organization / entity

Shahid Beheshti Medical University

Full name of responsible person

Soodeh Tabashi

Position

Resident of Anesthesiology

Latest degree

Medical doctor

Other areas of specialty/work**Street address**

No. 26, 6th alley, Vozara St.

City

Tehran

Province

Tehran

Postal code

1511738843

Phone

+98 912 205 6971

Fax**Email**

soodeh.tabashi@yahoo.com

Web page address

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shahid Beheshti Medical University

Full name of responsible person

Dr Noor Mohammad Arefian

Position

Associate Professor

Latest degree

Specialist

Other areas of specialty/work**Street address**

Erabi St., Yaman St., Chamran highway

City

Tehran

Province

Tehran

Postal code

1985717443

Phone

+98 21 2274 9201

Fax**Email**

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

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available