

# 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/m<sup>2</sup> candidate for gastric bypass surgery  
Body mass Index > 35kg/m<sup>2</sup> 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

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## Person responsible for updating data

### Contact

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**Latest degree**

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## Person responsible for scientific inquiries

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**Name of organization / entity**

Shahid Beheshti Medical University

**Full name of responsible person**

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**Position**

Associate Professor

**Latest degree**

Specialist

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

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**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