

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

14 Jun 2026

### Addition of a very low dose of naloxone to remifentanyl infusion on postoperative pain in patients undergoing total hip replacement surgery

#### Protocol summary

##### Study aim

Determining the effect of adding low dose naloxone to remifentanyl infusion on the postoperative pain of patients undergoing total hip replacement surgery.

##### Design

A randomized double-blinded clinical trial with Parallel groups, phase 2-3 on 80 patients

##### Settings and conduct

Patients were admitted for total hip joint replacement in the operating room of Qaem and Imam Reza hospitals, in a double-blind method (The patients were unaware of the type of substance used (naloxone or remifentanyl) and the evaluator of the study outcomes was also unaware of which outcome was related to the intervention or control group), Patients were divided into two groups, intervention group included: Naloxan infusion at a dose of 0.25 µg/kg/h to an amount that reduces the incidence of side effects caused by the use of remifentanyl (dose 0.30 µg/kg/min) after surgery.

##### Participants/Inclusion and exclusion criteria

Inclusion criteria: patients who undergo hip replacement surgery with general anesthesia, no chronic pain, age 18-65 years, physical status ASA I-II. Exclusion criteria: obesity (BMI ≥ 30 kg/m<sup>2</sup>), pregnancy, addiction to drugs and alcohol, use of any pain reliever in the last 24 hours, unusual bleeding, decrease or increase of blood pressure by more than 30% of the baseline value.f

##### Intervention groups

The intervention considered the infusion of naloxone at the dose of 0.25 µg/kg/h to the patients, in an amount that reduces the incidence of side effects caused by the use of remifentanyl (dose 0.30 µg/kg/min) in patients after surgery. And the control group received only remifentanyl (dose 0.30 µg/kg/min).

##### Main outcome variables

pain intensity

#### General information

##### Reason for update

Correction of typos recorded in the previous version

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT20220111053694N1**

Registration date: **2022-08-07, 1401/05/16**

Registration timing: **retrospective**

Last update: **2023-10-10, 1402/07/18**

Update count: **1**

##### Registration date

2022-08-07, 1401/05/16

##### Registrant information

###### Name

Saeid Jamalie

###### Name of organization / entity

###### Country

Iran (Islamic Republic of)

###### Phone

+98 51 3894 0696

###### Email address

jamaliehs971@mums.ac.ir

##### Recruitment status

**Recruitment complete**

##### Funding source

##### Expected recruitment start date

2021-02-19, 1399/12/01

##### Expected recruitment end date

2022-03-16, 1400/12/25

##### Actual recruitment start date

2021-02-28, 1399/12/10

##### Actual recruitment end date

2022-04-25, 1401/02/05

##### Trial completion date

2022-05-23, 1401/03/02

## Scientific title

Addition of a very low dose of naloxone to remifentanyl infusion on postoperative pain in patients undergoing total hip replacement surgery

## Public title

The effect of adding a very low dose of naloxone to remifentanyl infusion on pain

## Purpose

Treatment

## Inclusion/Exclusion criteria

### Inclusion criteria:

In this study, clinical trial of patients undergoing hip replacement surgery under general anesthesia No contraindications for general anesthesia No chronic pain Between 18 and 65 years With physical condition ASA I-II (scoring status Physical, American Society of Anesthesiologists) Filled out a written informed consent form

### Exclusion criteria:

Obesity (BMI  $\geq$  30 kg / m<sup>2</sup> ) Pregnancy (based on B-HCG check) Dependence on drugs and alcohol Use of any painkillers in the last 24 hours Unusual bleeding Ischemic heart disease History of seizures Decrease or increase in blood pressure by more than 30% of baseline Any surgical complications such as prosthetic fractures or enlargement of the surgery due to extensive fractures of the pelvis Postoperative exclusion criteria include reoperation Excessive bleeding Long-term ventilation (> 12 hours)

## Age

From **18 years** old to **65 years** old

## Gender

Both

## Phase

2-3

## Groups that have been masked

- Participant
- Outcome assessor

## Sample size

Target sample size: **80**

Actual sample size reached: **80**

## Randomization (investigator's opinion)

Randomized

## Randomization description

In this randomized clinical trial study, patients are randomly divided into groups with a ratio of 1:1 in two equal parts and using block randomization and sealed envelopes. allocation Concealment is done with a sealed envelope. The envelope method is that the envelopes will be prepared and printed by a member of the research team and random numbers with the help of Randomize.com and placed inside the envelope. The lid of the envelopes will be closed and its contents will not be visible from the outside.

## Blinding (investigator's opinion)

Double blinded

## Blinding description

In this study, patients and outcome assessors were unaware of the intervention and control groups.

## Placebo

Not used

## Assignment

Parallel

## Other design features

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics Committee of Mashhad University of Medical Sciences

##### Street address

Department of anesthesia, Qaem Hospital, Ahmedabad Blvd, Mashhad, Iran.

##### City

Mashhad

##### Province

Razavi Khorasan

##### Postal code

9178936683

#### Approval date

2021-01-20, 1399/11/01

#### Ethics committee reference number

IR.MUMS.MEDICAL.REC.1399.624

## Health conditions studied

### 1

#### Description of health condition studied

Patients undergoing complete hip replacement surgery

#### ICD-10 code

Z96.6

#### ICD-10 code description

Presence of orthopaedic joint implants

## Primary outcomes

### 1

#### Description

The patient's pain level

#### Timepoint

before the intervention and 4, 8, 12 and 24 hours after the intervention

#### Method of measurement

VAS scale (Based on this scale, a score between 1-10 is defined for the patient's pain)

## Secondary outcomes

### 1

#### Description

Need to be sedated

### **Timepoint**

The need for other painkillers after surgery to reduce the patient's pain

### **Method of measurement**

Checklist

## **2**

### **Description**

Time to first sedative

### **Timepoint**

after surgery

### **Method of measurement**

Checklist based on the patient's needs and pain

## **3**

### **Description**

Cumulative dose of painkiller used

### **Timepoint**

The first 24 hours after the surgery

### **Method of measurement**

Checklist (total dose used)

## **Intervention groups**

### **1**

### **Description**

Intervention group: In the intervention group, naloxone (Caspian tamin pharmaceutical co) with a very low dose (0.05 µg/kg/h) was added to remifentanyl (Exir pharmaceutical co) infusion (with a dose of 0.3 µg/kg/min) as IV and through a continuous injection pump until the end of the operation in Patients undergoing total hip replacement surgery. The treatment method is based on the effect of narcotics on peripheral and central µ receptors and the effect of naloxone agonists and antagonists on these receptors.

### **Category**

Treatment - Drugs

### **2**

### **Description**

Control group: Only remifentanyl (Exir pharmaceutical co) infusion at a dose of 0.3 µg/kg/min as IV and through a continuous injection pump until the end of the operation was prescribed for patients undergoing total hip replacement surgery.

### **Category**

Treatment - Drugs

## **Recruitment centers**

### **1**

### **Recruitment center**

#### **Name of recruitment center**

Imam Reza Hospital, Qaem Hospital

#### **Full name of responsible person**

Mohsen Saber Moghadam Ranjbar

### **Street address**

Ahmedabad Boulevard, Shariati Square

### **City**

Mashhad

### **Province**

Razavi Khorasan

### **Postal code**

9178936683

### **Phone**

+98 51 3841 7402

### **Email**

dr.saeidjamalie@gmail.com

## **Sponsors / Funding sources**

### **1**

### **Sponsor**

#### **Name of organization / entity**

Mashhad University of Medical Sciences

#### **Full name of responsible person**

Mohsen Saber Moghadam Ranjbar

#### **Street address**

Azadi Square, Mashhad University of Medical Sciences

#### **City**

Mashhad

#### **Province**

Razavi Khorasan

#### **Postal code**

9178936683

#### **Phone**

+98 51 3858 3878

#### **Email**

dr.saeidjamalie@gmail.com

### **Grant name**

### **Grant code / Reference number**

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

Yes

### **Title of funding source**

Mashhad 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**

Mashhad University of Medical Sciences

#### **Full name of responsible person**

Saeid Jamalie Bastami

#### **Position**

Anesthesiology resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

**Street address**

50 Sayad St., No. 28

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9197815861

**Phone**

+98 51 3884 4186

**Email**

dr.saeidjamalie98@gmail.com

**Person responsible for scientific inquiries****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

**Full name of responsible person**

Saeid Jamalie bastami

**Position**

Anesthesiology resident

**Latest degree**

Medical doctor

**Other areas of specialty/work**

Anesthesiology

**Street address**

50 Sayad St., No. 28

**City**

Mashhad

**Province**

Razavi Khorasan

**Postal code**

9197815861

**Phone**

+98 51 3884 4186

**Email**

drr.saeidjamalie@gmail.com

**Person responsible for updating data****Contact****Name of organization / entity**

Mashhad University of Medical Sciences

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Saeid Jamalie Bastami

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Anesthesiology resident

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Medical doctor

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**Postal code**

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**Phone**

+98 51 3884 4186

**Email**

dr.saeidjamalie@gmail.com

**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