Clinical Trial Protocol
Iranian Registry of Clinical Trials

14 Jun 2026

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

Protocol summary

Study aim
Determining the effect of adding low dose naloxone to remifentanil 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 remifentanil) 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 remifentanil (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/m2), 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 remifentanil (dose 0.30 µg/kg/min) in patients after surgery. And the control group received only remifentanil (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
jamaliehbs971@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 remifentanil infusion on postoperative pain in patients undergoing total hip replacement surgery

Public title
The effect of adding a very low dose of naloxone to remifentanil 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 ≥ 30 kg / m2) 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 Randomaize.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 remifentanil (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 µu receptors and the effect of naloxone agonists and antagonists on these receptors.
Category
Treatment - Drugs

2

Description
Control group: Only remifentanil (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
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
9178936683
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