Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 2026

Effect of adding Ketamine to the morphine in patients addicted to opioid post orthopedic operation pain

Protocol summary

Summary

The aim of this study was to evaluate the effect of adding Ketamine to the morphine in patients addicted to opioid post orthopedic operation pain. The inclusion criterias of this double blind clinical trial are patients in the range of 20-60 years old undergoing orthopedic operation with ASA I-II and history of opioid consumption. Exclusion criterias are history of psychiatric disease, using palliative drugs ,chronic pain.Sample size and population: 60 patients in the range of 20-60 years old , undergoing orthopedic operation with history of opioid consumption. The patients were randomly divided in two groups. Post operation, the first group received morphine 20 mg and the second group received morphine 20 mg + Ketamin 100 mg via IV patient-controlled analgesia (IPCA). The pain score as visual analogue scale (VAS), sedation score with ramsay scale, and nausea and vomiting were evaluated at 1, 6, 12 and 24 hours post operation.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017101636822N1**
Registration date: **2017-10-26, 1396/08/04**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2017-10-26, 1396/08/04

Registrant information

Name

Najmeh Najafi

Name of organization / entity

Yazd Shahid Sadoughi University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 35 3820 3410

Email address

drhahosseini@ssu.ac.ir

Recruitment status

Recruitment complete

Funding source

Yazd Shahid Sadoughi University Of Medical Sciences
Person responsible fore scientific inquiries:Habibollah hosseini

Expected recruitment start date

2016-06-18, 1395/03/29

Expected recruitment end date

2016-09-14, 1395/06/24

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effect of adding Ketamine to the morphine in patients addicted to opioid post orthopedic operation pain

Public title

Effect of Ketamine on post operation pain

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: addict patients؛ age of 20-60 years old؛ ASA I-II ؛undergoing orthopedic operation Exclusion criteria: sevsre obesity؛ history of psychiatric disease؛ using palliative or psychedelic drugs؛ chronic pain and upper respiratory tract infection

Age

From **20 years** old to **60 years** old

Gender

Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **60**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Not used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Yazd Shahid Sadoughi University Of Medical Sciences
Street address
Yazd Shahid Sadoughi University Of Medical Sciences
City
Yazd
Postal code
8915173160
Approval date
2016-10-20, 1395/07/29
Ethics committee reference number
IR.SSU.medicine.REC.1395.193

Health conditions studied

1

Description of health condition studied
General Anaesthetics
ICD-10 code
Y48.2
ICD-10 code description
Other and unspecified general anaesthetics

Primary outcomes

1

Description
Morphine Dose
Timepoint
24 hour after operation
Method of measurement
Milligram

2

Description
Pain Score
Timepoint
1,6,12,24 hours after operation
Method of measurement
Visual Analogue Scale

3

Description
Sedation Score
Timepoint
1,6,12,24 hours after operation
Method of measurement
Ramsay Scale

Secondary outcomes

1

Description
Nausea & Vomiting Score
Timepoint
1,6,12,24 hours after operation
Method of measurement
Nausea & Vomiting Scale

Intervention groups

1

Description
The first groupe after spinal anesthesia with 2.5 ml of Marcaine 0.5% and 20 mg intravenous of midazolam as sedation, were underwent the orthopedic operation. Post operation they received morphine 20 mg via IV patient-controlled analgesia (IPCA). the scores measured in 1, 6, 12, 24 hours after operatin.
Category
Treatment - Drugs

2

Description
The second groupe after spinal anesthesia with 2.5 ml of Marcaine 0.5% and 20 mg intravenous of midazolam as sedation, were underwent the orthopedic operation. Post operation they received morphine 20 mg+ ketamine 100 mg via IV patient-controlled analgesia (IPCA). the scores measured in 1, 6, 12, 24 hours after operatin.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Yazd Shahid Sadoughi Hospital
Full name of responsible person
Habibollah Hossieni, anesthesiologist
Street address
Yazd Shahid Sadoughi Hospital
City
Yazd

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Yazd Shahid Sadoughi University Of Medical Sciences
Full name of responsible person
Mahmood Vakili
Street address
Yazd Shahid Sadoughi University Of Medical Sciences
City
Yazd
Grant name
o
Grant code / Reference number
0
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Yazd Shahid Sadoughi University Of Medical Sciences
Proportion provided by this source
100
Public or private sector
empty
Domestic or foreign origin
empty
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
empty

Person responsible for general inquiries

Contact
Name of organization / entity
Yazd Shahid Sadoughi University Of Medical Sciences
Full name of responsible person
Najmeh Najafi
Position
Medical Doctor
Other areas of specialty/work
Street address
Yazd Shahid Sadoughi University Of Medical Sciences
City
Yazd
Postal code
8915173160
Phone
+98 35 3725 8770
Fax
+98 37240371
Email
najafi.n22@gmail.com
Web page address
ssu.ac.ir

Person responsible for scientific inquiries

Contact
Name of organization / entity
Yazd Shahid Sadoughi University Of Medical Sciences
Full name of responsible person
Habibollah Hosseini
Position
Anesthesiologist
Other areas of specialty/work
Street address
Yazd Shahid Sadoughi University Of Medical Sciences
City
Yazd
Postal code
8915173160
Phone
+98 35 3725 8770
Fax
+98 37240371
Email
drhahosseini@ssu.ac.ir
Web page address
www.ssu.ac.ir

Person responsible for updating data

Contact
Name of organization / entity
Yazd Shahid Sadoughi University Of Medical Sciences
Full name of responsible person
Najmeh Najafi
Position
Medical Doctor
Other areas of specialty/work
Street address
Yazd Shahid Sadoughi University Of Medical Sciences
City
Yazd
Postal code
8915173160
Phone
+98 35 3725 8770
Fax
+98 37240371
Email
najafi.n22@gmail.com
Web page address
www.ssu.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)
empty
Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty