Clinical Trial Protocol
Iranian Registry of Clinical Trials

30 Jun 2026

Evaluation of the effect of Methyl-Naltrexone in reducing urinary retention after orthopedic surgeries under spinal anesthesia by Bupivacaine and Morphine

Protocol summary

Summary

Methylnaltrexone has proved by FDA as peripheral antagonist of μ receptors in the body, which can significantly decrease narcotic side effects in peripheral organs (constipation,...). It can not decline analgesic effect of narcotics. Intrathecal morphine uses routinely in orthopedic surgeries (lower extremities); so it is expected that using subcutaneous injection of methyl Naltrexone can largely prevent peripheral side-effects of opioids such as urinary retention , constipation, nausea and vomiting, and impaired gastric emptying. This study will be perform on 70 (regarding to similar articles) 18-50 years old patients, schedule for elective lower limb orthopedic surgeries who have traditional scientific indications for spinal anesthesia . Over 50 years of age is a predisposing factor for postoperative urinary retention ;So patients over age 50 will not be enrolled. In this study we will evaluate reduction of these side effects (especially urinary retention) by use methyl Naltrexone in 35 patients (18-50 years old, without history of addiction or psychological problems) undergoing spinal anesthesia with intrathecal administration of bupivacaine and morphine and compare with the second group (35 patients, 18-50 years old, undergoing the same spinal anesthesia without methyl Naltrexone). Then, all patients will be followed for 24 hours postoperatively (every 1 hour), and morphine side-effects (central and peripheral) will be evaluate and compare between two groups. Obviously, if achieve positive results , this drug can reduce complications after surgery with spinal anesthesia.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201204145172N3**

Registration date: **2012-07-07, 1391/04/17**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2012-07-07, 1391/04/17

Registrant information

Name

Saman Asadi

Name of organization / entity

Anesthesiology ward of Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Email address

asadisa@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences, Anesthesiology Research Center

Expected recruitment start date

2012-07-22, 1391/05/01

Expected recruitment end date

2012-09-22, 1391/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Evaluation of the effect of Methyl-Naltrexone in reducing urinary retention after orthopedic surgeries under spinal anesthesia by Bupivacaine and Morphine

Public title
Effect of a new drug (Methyl-Naltrexone) in reducing urinary complication after use of Morphine
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:18 – 50 years old patient ; planned orthopedic surgery on lower Extremities; usual criteria for spinal anesthesia Exclusion Criteria : Peri-op Int. folley; Genito-urinary problems (Benign prostatic hyperplasia, Urinary stone, Renal failure, …); Addiction (in 6 mounts before operation) ; Use of opioids in 12 hours before operation; Neurologic Disease (stroke, alcohol/diabete neuropathies, cerebral palsy, spinal lesions, multiple sclerosis, poly myositis); Drugs (anti-cholinergics, β-blockers, Sympathomimetics, α-agonists/antagonists)
Age
From **18 years** old to **50 years** old
Gender
Both

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **70**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Triple blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics committee of Shiraz University of Medical Sciences
Street address
Shiraz University of Medical Sciences
City
Shiraz
Postal code
Approval date
2012-01-21, 1390/11/01
Ethics committee reference number
CT-902528

Health conditions studied

1

Description of health condition studied
Urinary Retention
ICD-10 code
N39.9
ICD-10 code description
Disorder of urinary system, unspecified

Primary outcomes

1

Description
urinary retention
Timepoint
every 1 hour till 24 hours after surgery
Method of measurement
By a questionnaire of urinary retention: a) the patient's inability to pass urine after surgery, despite feeling a need to urinating for half an hour and leaving every amount of urine after catheterization. B) inability to pass urine for 12 hours after surgery, without feeling a need to urinating and leaving at least 600 cc of urine after catheterization.

Secondary outcomes

1

Description
Itching
Timepoint
every 1 hour till 24 hours after surgery
Method of measurement
By a questionnaire of itching: incidence of itching to the extent that the patient seek treatment.

2

Description
nausea, vomiting
Timepoint
every 1 hour till 24 hours after surgery
Method of measurement
By a questionnaire of nausea and vomiting: a) the incidence of nausea in the interval 4 to 24 hours after surgery (each of which is questioned by a trained nurse), b)vomit the stomach contents in 4 to 24 hours after surgery.

3

Description
respiratory suppression
Timepoint
every 1 hour till 24 hours after surgery

Method of measurement
By a questionnaire of suppressed breathing, reduced respiratory rate less than 8 per minutes for 24 hours after surgery (each hour can be recorded by trained nurses)

4

Description
decreased level of consciousness
Timepoint
every 1 hour till 24 hours after surgery
Method of measurement
By a questionnaire of decreased level of consciousness: drowsiness or dizziness that each hour until 24 hours after surgery are recorded by trained nurses.

Intervention groups

1

Description
As usual anesthetic protocol,10 mg intrathecal bupivacaine 0.5% and 0.1 are injected; immediately, 12mg methyl Naltrexone subcutaneously (by a trained nurse who is unaware of any drugs) will be administered to patients in the first group. Then during surgery and 24 hours after it, symptoms such as urinary retention, nausea and vomiting, itching, respiratory suppression and decreased level of consciousness are investigated
Category
Prevention

2

Description
As usual anesthetic protocol,10 mg intrathecal bupivacaine 0.5% and 0.1 are injected; immediately, placebo subcutaneously (by a trained nurse who is unaware of any drugs) will be administered to patients in the second group. Then during surgery and 24 hours after it, symptoms such as urinary retention, nausea and vomiting, itching, respiratory suppression and decreased level of consciousness are investigated
Category
Prevention

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Chamran Hospital
Full name of responsible person
Saman Asadi, MD
Street address
Anestheiology office, Shahid Faghihi Hospital, Shiraz
City
Shiraz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Dr Poost Foroosh
Street address
Shiraz University of Medical Sciences
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shiraz 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
Shiraz University of Medical Sciences
Full name of responsible person
Saman Asadi, MD
Position
Anesthesiology resident
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Person responsible for scientific inquiries

Contact
Name of organization / entity
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Farid Zand, MD

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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