

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

+98 71 1231 8072

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

Anesthesiology 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

Other areas of specialty/work

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Person responsible for scientific inquiries

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Web page address**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