

# Clinical Trial Protocol

## Iranian Registry of Clinical Trials

12 Jun 2026

### Comparison of analgesia with and without the addition of Dex Methomedin to bupivacaine spinal anesthesia for orthopedic surgery using TOTAL KNEE

#### Protocol summary

##### Summary

The aims of this study included: compare of mean the amount of pain after surgery based VAS in the two groups of study in defined times, compare of mean the amount of Analgesic use in patients in first 24 h in the two groups of study and compare of The mean time to completion of the operation the patient's first request for pain medication in the two groups of study. This double-blind study randomly assigned to two groups (case & control) with 128 participant. Inclusion criteria is: 18-45 years old and ASA Class 1&2. Exclusion criteria is: A history of cardiovascular disease, asthma, diabetes, kidney or liver disease or any systemic disease. Patients are transferred to the operating room for surgery and placed under spinal anesthesia with a uniform approach. In all cases the patient in the sitting position solution provided worked through the spinal needle numbers 25 Will be administered by an anesthesiologist on duty. Case group receive Bupivacaine (2.5cc) plus 5mg Dexmedetomidine (0.5cc) and control group receive Bupivacaine (2.5cc) plus Saline (0.5cc). Assumed pain in times 1, 2, 6, 12, 24 after operating, The amount of Narcotic administration 24 hour after operating And time to first analgesic administration And assessed side effects are dry mouth, nausea, vomiting.

#### General information

##### Acronym

##### IRCT registration information

IRCT registration number: **IRCT2016112430808N2**  
Registration date: **2017-02-13, 1395/11/25**  
Registration timing: **retrospective**

Last update:

Update count: **0**

##### Registration date

2017-02-13, 1395/11/25

##### Registrant information

###### Name

Yousef Hosseini

###### Name of organization / entity

Jahrom University of Medical Sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 917 816 6606

###### Email address

y.hosseini@jums.ac.ir

##### Recruitment status

###### Recruitment complete

##### Funding source

Vice chancellor for research, Jahrom university of Medical Science

##### Expected recruitment start date

2015-09-19, 1394/06/28

##### Expected recruitment end date

2016-09-18, 1395/06/28

##### Actual recruitment start date

empty

##### Actual recruitment end date

empty

##### Trial completion date

empty

##### Scientific title

Comparison of analgesia with and without the addition of Dex Methomedin to bupivacaine spinal anesthesia for orthopedic surgery using TOTAL KNEE

##### Public title

Comparison of analgesia with and without the addition of Dex Methomedin to bupivacaine spinal anesthesia for orthopedic surgery using TOTAL KNEE

## Purpose

Treatment

## Inclusion/Exclusion criteria

Inclusion Criteria: aged 18 to 45 years old, Class 1 and 2  
ASA Exclusion Criteria: A history of cardiovascular disease, asthma, diabetes, kidney or liver disease or any systemic disease. History of narcotics, alcohol, anti-epileptic drugs, antipsychotic, analgesic. Patients who have severe pain during surgery and general anesthesia are forced to use

## Age

From **18 years** old to **45 years** old

## Gender

Both

## Phase

2-3

## Groups that have been masked

*No information*

## Sample size

Target sample size: **128**

## Randomization (investigator's opinion)

Randomized

## Randomization description

## Blinding (investigator's opinion)

Double blinded

## Blinding description

## Placebo

Used

## Assignment

Parallel

## Other design features

Cohen table

## Secondary Ids

empty

## Ethics committees

### 1

#### Ethics committee

##### Name of ethics committee

Ethics committee of jahrom University of Medical Sciences

##### Street address

Motahari Street, Jahrom University of Medical Sciences, Jahrom, Fars, Iran Jahrom

##### City

جهرم

##### Postal code

#### Approval date

2016-10-05, 1395/07/14

#### Ethics committee reference number

IR.JUMS.REC.1395.060

## Health conditions studied

### 1

#### Description of health condition studied

Analgesia after surgery

#### ICD-10 code

R52

#### ICD-10 code description

Acute pain

## Primary outcomes

### 1

#### Description

pain score

#### Timepoint

in 1,2,6,12,24 hour post operation

#### Method of measurement

pain assessment ruler

## Secondary outcomes

### 1

#### Description

Blood pressure

#### Timepoint

1,2,6,12, 24 hours after surgery

#### Method of measurement

Blood pressure measuring device

### 2

#### Description

Pulse rate

#### Timepoint

1,2,6,12, 24 hours after surgery

#### Method of measurement

Pulse oximetry

### 3

#### Description

The Chills, oral dryness, nausea and vomiting

#### Timepoint

1,2,6,12, 24 hours after surgery

#### Method of measurement

use of a questionnaire researcher

### 4

#### Description

The rate of post-operative pain medication use

#### Timepoint

1,2,6,12, 24 hours after surgery

#### Method of measurement

total dose administered by injection(mg)

## Intervention groups

### 1

#### Description

case group received 2.5 bupivacaine plus 0.5 Dax medetomidine

**Category**

Treatment - Drugs

**2****Description**

control group received 12.5 bupivacaine ml plus 2.5 normal saline

**Category**

Treatment - Drugs

**Recruitment centers****1****Recruitment center****Name of recruitment center**

peymanieh Hospital

**Full name of responsible person**

Navid Kalani

**Street address**

Jahrom University Of Medical University

**City**

Jahrom

**Sponsors / Funding sources****1****Sponsor****Name of organization / entity**

Vice Chancellor for research of jahrom University of Medical Sciences

**Full name of responsible person**

Kavoos Solhjo

**Street address**

Motahari Street, Jahrom University of Medical Sciences, Jahrom, Fars, Iran Jahrom

**City**

jahrom

**Grant name****Grant code / Reference number****Is the source of funding the same sponsor organization/entity?**

Yes

**Title of funding source**

Vice Chancellor for research of jahrom 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**

Jahrom University of Medical Sciences

**Full name of responsible person**

navid kalani

**Position**

clerk

**Other areas of specialty/work****Street address**

Motahari Street, Jahrom University of Medical Sciences, Jahrom, Fars, Iran Jahrom

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Department of Anesthesiology

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**Position**

Bachelor

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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*