

Clinical Trial Protocol

Iranian Registry of Clinical Trials

17 Sep 2026

Comparative study of intrathecal dexmedetomidine and su fentanyl as adjuvants to Bupivacaine in Dynamic hip screw operations

Protocol summary

Summary

Aim of this study is comparative intrathecal dexmedetomidine and sufentanyl as adjuncts to Bupivacaine in Dynamic hip screw operations. This study is clinical trials and double blind. We will enter 80 patients with Dynamic hip screw operations in Valiasr hospital. We will divide patients in two groups randomly (each group 40 patients). We will inject 8 milligram Bupivacaine and 5 microgram dexmedetomidine in first group and We will inject 8 milligram Bupivacaine and 2.5 microgram sufentanyl in second group. We will check motor blocks every 20 minute. Researcher will check pain in 1 and 2 and 6 and 12 and 24 hours after surgery. The amount of Apotel needed in 24 hours after surgery, will be measured. Inclusion criteria: 20 to 60 years; Dynamic hip screw operations Exclusion criteria: allergy to dexmedetomidine and Bupivacaine ;breastfeeding women; hepatic and renal and cardiovascular disease; history of addiction; diabetes; long-term use of analgesics; taking Psychiatric Drug; anticoagulant; deformity of the spine; coagulation disorders; skin infection in site of spinal block

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017050220258N45**

Registration date: **2017-08-04, 1396/05/13**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-08-04, 1396/05/13

Registrant information

Name

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Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor and Research, Arak University of Medical Sciences

Expected recruitment start date

2016-04-25, 1395/02/06

Expected recruitment end date

2018-04-26, 1397/02/06

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparative study of intrathecal dexmedetomidine and su fentanyl as adjuvants to Bupivacaine in Dynamic hip screw operations

Public title

Effect of dexmedetomidine and su fentanyl as adjuvants to Bupivacaine in Dynamic hip screw operations

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 20 to 60 years; Dynamic hip screw operations Exclusion criteria: allergy to dexmedetomidine and Bupivacaine ;breastfeeding women; hepatic and renal and cardiovascular disease;

history of addiction; diabetes; long-term use of analgesics; taking Psychiatric Drug; anticoagulant; deformity of the spine; coagulation disorders; skin infection in site of spinal block

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

Gender
Both

Phase
2-3

Groups that have been masked
No information

Sample size
Target sample size: **80**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Double blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features
Randomize with random numbers table blinding: patients and analyzer and person that complete questionnaire were unaware of group assignment

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee Arak University Of Medical Sciences

Street address
Vice chancellor for research, Payambar azam complex, Basij square, Sardasht, Arak

City
Arak

Postal code
38149578558

Approval date
2016-04-25, 1395/02/06

Ethics committee reference number
IR.ARAKMU.REC.1395.32

Health conditions studied

1

Description of health condition studied
fracture of hip

ICD-10 code
S72.0

ICD-10 code description

Fracture of neck of femur

Primary outcomes

1

Description
motor block

Timepoint
every 20 minute

Method of measurement
bromeg scale

2

Description
pain

Timepoint
1 and 2 and 6 and 12 and 24 hours after surgery

Method of measurement
Visual Analog Scale

3

Description
use Apotel

Timepoint
in 24 hours after surgery

Method of measurement
milligram

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group:We will inject 8 milligram Bupivacaine and 5 micro gram dexmedetomidine in first group .

Category
Treatment - Drugs

2

Description
Intervention group:We will inject 8 milligram Bupivacaine and 2.5 micro gram sufentanyl in second group.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Valiasr Hospital

Full name of responsible person
Dr Bijan Yazdi

Street address

Valiasr hospital, Valiasr square

City

Arak

Web page address

-

Sponsors / Funding sources1**Sponsor****Name of organization / entity**

Vice chancellor for research, Arak University of Medical Sciences

Full name of responsible person

Dr Mohammad Rafiee

Street address

Vice chancellor for research, Payambar Azam Complex, Basij square, Sardasht, Arak

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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, Arak 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**

Arak University of Medical Sciences

Full name of responsible person

Dr Hesamodin Modir

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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