

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Efficacy of Dexmedetomidine and Ketamin in Epidural Anesthesia to Bupivacaine %0.25 to reduce postoperative Analgesia in fracture femur.

Protocol summary

Summary

Aim of this study: efficacy of Dexmedetomidine and Ketamin in Epidural anesthesia to Bupivacaine %0.25 to reduce postoperative analgesia in femur fracture. 105 patients with femur fracture divided randomly to three groups Dexmedetomidine and Ketamin and placebo (35 patient). We injected 0/5 gram Dexmedetomidine (30-35 gram) in first group and 25 milligram Ketamin (0/5 milliliter) in second group and 0/5 milliliter normal saline (0/5 milliliter) in control group. Vital sign recorded every 5 minute to 15 minute and every 15 minutes to 1 hour in surgery. We recorded vital sign and score of pain with Visual Analog scale in recovery. We recorded duration analgesia and score of pain in 4 and 12 and 24 hours after surgery and average of narcotic drug after surgery. Inclusion criteria: age between 40-85 years; ASA I and II; no sensitivity to drugs; no history of substance abuse; lack of epidural contraindications; duration of surgery 90-120 minute. Exclusion criteria: body mass index 35 and more; general anesthesia; duration surgery more than 120 minute; other fracture; chronic disease.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2016102620258N16**

Registration date: **2016-11-15, 1395/08/25**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2016-11-15, 1395/08/25

Registrant information

Name

Fariba Farokhi

Name of organization / entity

Arak University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research, Arak University of Medical Sciences

Expected recruitment start date

2016-10-07, 1395/07/16

Expected recruitment end date

2018-10-08, 1397/07/16

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Efficacy of Dexmedetomidine and Ketamin in Epidural Anesthesia to Bupivacaine %0.25 to reduce postoperative Analgesia in fracture femur.

Public title

Efficacy of Dexmedetomidine and Ketamin in Epidural Anesthesia to Bupivacaine %0.25 to reduce postoperative Analgesia in fracture femur.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: age between 40-85 years; ASA I and II; lack of sensitivity to drugs; lack of substance abuse; lack of epidural contraindications; duration of surgery 90-120 minute. Exclusion criteria: body mass index 35 and more;

need to general anesthesia; duration surgery more than 120 minute; other fracture; chronic disease.

Age

From **40 years** old to **85 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **105**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Parallel

Other design features

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

848176941

Approval date

2016-08-22, 1395/06/01

Ethics committee reference number

IR.ARAKMU.MU.REC.1395.210

Health conditions studied

1

Description of health condition studied

Femur fracture

ICD-10 code

S72.0

ICD-10 code description

Fracture of neck of femur

Primary outcomes

1

Description

Heart rate

Timepoint

Every 5 minute to 15 minute and every 15 minute to 1 hour in surgery and in recovery

Method of measurement

Count in minute

2

Description

Respiratory rate

Timepoint

Every 5 minute to 15 minute and every 15 minute to 1 hour in surgery

Method of measurement

Count in minute

3

Description

Blood pressure

Timepoint

Every 5 minute to 15 minute and every 15 minute to 1 hour in surgery and in recovery

Method of measurement

Sphygomanometer

4

Description

Pain

Timepoint

At recovery room and 4 and 12 and 24 hours after surgery

Method of measurement

Visual Analogue Scale

5

Description

Mean of narcotic needed

Timepoint

24 hour after surgery

Method of measurement

milligram

Secondary outcomes

empty

Intervention groups

1

Description

We injected 0/5 geram Dexmedetomidine (30-35 geram) in first group .

Category

Treatment - Drugs

2

Description

We injected 25 milligram Ketamin (0/5 milliliter) in second group.

Category

Treatment - Drugs

3

Description

We injected 0/5 milliliter normal saline (0/5 milliliter) in control group.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital

Full name of responsible person

Dr Alireza Kamali

Street address

Valiasr Hospital, Arak

City

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Sponsors / Funding sources

1

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

City

Arak

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

Faculty of Medicine

Full name of responsible person

Dr Taraneh Radbin

Position

Resident of Anesthesiology

Other areas of specialty/work

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Person responsible for scientific inquiries

Contact

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Faculty of Medicine

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Position

Anesthesiologist

Other areas of specialty/work

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Person responsible for updating data

Contact

Name of organization / entity

Arak University of Medical Sciences

Full name of responsible person

Dr Taraneh Radbin

Position

resident of anesthesiology

Other areas of specialty/work

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Web page address**Sharing plan****Deidentified Individual Participant Data Set (IPD)**

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Study Protocol

empty

Statistical Analysis Plan

empty

Informed Consent Form

empty

Clinical Study Report

empty

Analytic Code

empty

Data Dictionary

empty