

Clinical Trial Protocol

Iranian Registry of Clinical Trials

06 Jun 2026

A Comparison between neostigmin and ketamin as adjvant with bupivacain 0.25% in epidural method for post operative pain control in patient with femoral fracture and candidate for elective surgery

Protocol summary

Summary

The purpose of this study is to compare the effects of neostigmine and ketamine added to bupivacaine 25/0% in the epidural analgesia after surgery in patients with femoral fractures are candidates for non-emergency surgery. This study is a double blind Randomized clinical trial that perform on patient candidated for elective femoral surgery with mentioned above criteria. In this study, all patients over age 50 are candidates for elective surgery and the ASA are rated Class 1 and 2. All of them randomizedly divided in three groups. A(neostigmine), B(ketamin), C(placebo). Pain score check for all patient in recovery and 6,12 and 24 hours after sergury. During sergury BP,PR, HR, O2Sat and ECG record evrey 5 minutes. Evrey group containe 30 patient. All data analyze with statistical software.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201112198468N1**
Registration date: **2012-04-25, 1391/02/06**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2012-04-25, 1391/02/06

Registrant information

Name

Abbas Zareei

Name of organization / entity

Arak medicl university

Country

Iran (Islamic Republic of)

Phone

+98 86 1313 6055

Email address

dr.zarei@arakmu.ac.ir

Recruitment status

Recruitment complete

Funding source

Arak University Of Medical Sciences

Expected recruitment start date

2012-03-20, 1391/01/01

Expected recruitment end date

2012-09-20, 1391/06/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A Comparison between neostigmin and ketamin as adjvant with bupivacain 0.25% in epidural method for post operative pain control in patient with femoral fracture and candidate for elective surgery

Public title

A Comparison between neostigmin and ketamin as adjvant with bupivacain 0.25% in epidural method for post operative pain control in patient with femoral fracture and candidate for elective surgery

Purpose

Other

Inclusion/Exclusion criteria

Inclusion criteria:Age above 50 y/o, ASA class 1 and 2, Elective sergury candidate, No sensitivity to local anesthetic, No contrandication to rgional anesthesia, Exclusion criteria: Sergury above 2hours, Failuer of epidural anesthesia, Concomitant fracture, Fever and

infection

Age

From **50 years** old to **100 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **90**

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

Arak University Of Medical Science

Street address

Basij Square

City

Arak

Postal code

3819693345

Approval date

2011-07-04, 1390/04/13

Ethics committee reference number

2-109-90

Health conditions studied

1

Description of health condition studied

Femor Fracture Sergery

ICD-10 code

S72

ICD-10 code description

Fracture of femur

Primary outcomes

1

Description

Pain Scre

Timepoint

During serger, in recovery,6and 12 and 24 hours after sergery

Method of measurement

Visual Analog Sore

Secondary outcomes

1

Description

Vital Sign: BP,HR PR O2Sat,ECG

Timepoint

During serger,in recovery,6and 12 and 24 hours after sergery

Method of measurement

Electronic Monitoring Device

Intervention groups

1

Description

group A; neostigmine 60 mcg added to 2cc/segment of 0.25% bopivacaine in atotal volume 20cc with water for injectin

Category

Treatment - Drugs

2

Description

group B; KETAMIN 40 mg added to 2cc/segment of 0.25% bopivacaine in atotal volume 20cc with water for injectin

Category

Treatment - Drugs

3

Description

group C; only 2cc/segment of 0.25% bopivacaine in atotal volume 20cc with water for injectin

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Valiasr Hospital

Full name of responsible person

DrAbbas Zareei

Street address

Valiasr Hospital

City

Arak

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Arak University Of Medical Sciences

Full name of responsible person

Dr saed Changizi Ashtiyani

Street address

A'lam,Al-Hoda Street, Shahid Shiroodi Street, Arak,
Markazi Province, Iran

City

Arak

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

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 Univesity Of Medical Sciences

Full name of responsible person

Dr Abbas Zareei

Position

MD/ Resident Of Anesthesiology

Other areas of specialty/work

Street address

Valiasr Hospital

City

Arak

Postal code

3819693345

Phone

+98 86 1223 1103

Fax

+98 86 1222 2003

Email

dr.zarei@arakmu.ac.ir

Web page address

www.portal.arakmu.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity

Arak University Of Medical Sciences

Full name of responsible person

Dr Esmaeil Moshiri

Position

Anesthesiologist

Other areas of specialty/work

Street address

Valiasr Hospital

City

Arak

Postal code

00988612231283

Phone

+98 86 1223 1103

Fax

+98 86 1222 2003

Email

Moshiri_e@yahoo.com

Web page address

www.portal.arakmu.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Arak University Of Medical Sciences

Full name of responsible person

Dr Abbas Zareei

Position

MD/ Resident Of Anesthesiology

Other areas of specialty/work

Street address

Valiasr Hospital

City

Arak

Postal code

3819693345

Phone

+98 86 1223 1103

Fax

+98 86 1223 1283

Email

dr.zarei@arakmu.ac.ir

Web page address

www.portal.arakmu.ac.ir

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