

Clinical Trial Protocol

Iranian Registry of Clinical Trials

11 Jul 2026

Comparison of the duration of sensory block and side effects of adding different doses of intrathecal fentanyl to lidocaine 5% in spinal anesthesia

Protocol summary

Summary

The aim of this study was to compare the duration of sensory and motor block and side effects of adding different doses of intrathecal fentanyl to lidocaine 5% in spinal anesthesia. Inclusion criteria were: patients undergoing elective surgery in lower abdomen and lower extremities under spinal anesthesia and need for anesthesia to level of T10 was enrolled in a double blind placebo-controlled clinical trial. Exclusion criteria: refusal of patient, infection of needle entrance, anatomical difficulty and neurologic diseases Patient recruitment: 140 patients enrolled in a double blind clinical trial and randomly allocated to 4 surgery groups. For spinal anesthesia in all patients, 100 mg of 5% intrathecal lidocaine was used and based on the drug added, patients were randomly assigned to one of four groups of control with adding 2 ml distilled water to lidocaine and injected to spinal space, case group 1 with adding 25 microgram fentanyl and 1.5 cc distilled water and injected to spinal space, case group 2 with adding 50 microgram fentanyl and 1 cc distilled water and injected to spinal space and case group 3 with adding 100 microgram fentanyl and injected to spinal space. Duration time of sensory and motor block and the occurrence of complications were evaluated.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201103303289N2**

Registration date: **2011-06-13, 1390/03/23**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2011-06-13, 1390/03/23

Registrant information

Name

Esmail Moshiri

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Deputy for research

Expected recruitment start date

2008-03-19, 1386/12/29

Expected recruitment end date

2009-03-20, 1387/12/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the duration of sensory block and side effects of adding different doses of intrathecal fentanyl to lidocaine 5% in spinal anesthesia

Public title

Effect of opioid on duration of spinal anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: age 15-65 y; physical status: ASA I and II; need for anesthesia below T10 Exclusion criteria: Patient refusal; Infection in needle entrance; Anatomical difficulty; Neurological diseases

Age

From **16 years** old to **65 years** old

Gender

Both

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **140**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Used

Assignment

Other

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Hamedan University of Medical Sciences

Street address

Mardom Park - Hamedan

City

Hamedan

Postal code

Approval date

2008-08-31, 1387/06/10

Ethics committee reference number

72229/9/35/16/پ

Health conditions studied

1

Description of health condition studied

local anesthesia

ICD-10 code

Y45.0, Y48

ICD-10 code description

Opioids and related analgesics,Local anaesthetics

Primary outcomes

1

Description

start of sensory block

Timepoint

before block every 1 min- then every 5 min

Method of measurement

cold sensation

2

Description

duration of sensory block

Timepoint

before block every 1 min- then every 5 min

Method of measurement

cold sensation

3

Description

start of motor block

Timepoint

every 5 min

Method of measurement

inability to move foot finger

4

Description

duration of motor block

Timepoint

every 5 min

Method of measurement

ability to move foot finger

Secondary outcomes

1

Description

end of sensory block

Timepoint

every 5 min

Method of measurement

cold sensation

2

Description

end of motor block

Timepoint

every 5 min

Method of measurement

moving fingers

Intervention groups

1

Description

control group:lidocaine 5%+distilled water 2 cc and injection to spinal space

Category

Treatment - Drugs

2**Description**

case group 1:lidocaine 5%+fentanyl 25 mic +distilled water 1.5 cc and injection to spinal space

Category

Treatment - Drugs

3**Description**

case group 2:lidocaine 5%+fentanyl 50 mic +distilled water 1 cc and injection to spinal space

Category

Treatment - Drugs

4**Description**

case group 3:lidocaine 5%+fentanyl 100 mic and injection to spinal space

Category

Treatment - Drugs

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

Hamedan University of Medical Sciences

Full name of responsible person

Ebrahim Khoshraftar,MD

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Operating Room- Besat Hospital- Hamedan

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Sponsors / Funding sources**1****Sponsor****Name of organization / entity**Hamedan University of Medical Sciences - Research
Deputy**Full name of responsible person**

Abbas Zamanian,MD

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Research Deputy - Medical Faculty - Hamedan

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Hamedan

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

Yes

Title of funding source

Hamedan University of Medical Sciences - Research

Deputy

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**

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Full name of responsible personEbrahim Khoshraftar,MD - Scientific Staff of Medical
Faculty - Anesthesia Group**Position**

Asspciated professor,Anesthetist

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Full name of responsible personEsmail moshiri,MD - Scientific Staff of Arak Medical
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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