Clinical Trial Protocol
Iranian Registry of Clinical Trials

06 Nov 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

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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 Scienses
Full name of responsible person
Ebrahim Khoshraftar,MD
Street address
Operating Room- Besat Hospital- Hamedan
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Hamedan University of Medical Scienses - Research Deputy
Full name of responsible person
Abbas Zamanian,MD
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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
Hamedan University of Medical Scienses - 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 person
Ebrahim Khoshraftar,MD - Scientific Staff of Medical Faculty - Anesthesia Group
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Person responsible for updating data

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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