

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the analgesic effects of one and two miligram bupivacaine added to intrathecal sufentanil on labor analgesia

Protocol summary

Summary

1)objective: Intrathecal analgesia in labor has become an established technique, and various local anesthetics and opioids have been used, either alone or in combination. The use of intrathecal bupivacaine with sufentanil has been described for labor, but dosages have been arbitrarily chosen with little knowledge of their contribution to the overall effectiveness of analgesia. The aim of this study was to assess the analgesic effects and possible side-effects of two different doses of intrathecal bupivacaine added to sufentanil in women in the first stage of labor. 2)Design: Randomized-double blinded placebo controlled clinical trial; one center; phase 2 clinical trial (3) Setting and conduct: we compared the analgesic effects and possible side-effects of different dosages of intrathecal bupivacaine (one and two milligram) added to 5 microgram sufentanil in 40 parturient women (20 patients in each group) in the first stage of labor. (4) Participants including major eligibility criteria: Inclusion criteria: ASA 1 primigravid singletone parturients with gestational age (36-40 wk) in active phase of labor. Exclusion criteria: Use of analgesic or opioids in recent 12 hours; chronic hypertension; preeclampsia; gestational diabetes; allergy to drugs; cardiovascular disease; coagulopathy. (5) Intervention: Spinal injection consisted 5 microgram sufentanil combined with 1 or 2 mg of bupivacaine from the L4-L5 or L3-L4 interspace with the patient in the sitting position. (6) main outcome measures (variables): onset of analgesia and time from spinal injection until the relief of labor pain wich were measured every 5 minutes after spinal injection in the first 15 min after spinal injection

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201701168768N5**

Registration date: **2017-02-07, 1395/11/19**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2017-02-07, 1395/11/19

Registrant information

Name

Mahshid Nikooseresht

Name of organization / entity

Hamadan university of Medical Sciences, Faculty of Medicine

Country

Iran (Islamic Republic of)

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nikooseresht@umsha.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for Research and Technology, Hamadan University Of Medical Sciences

Expected recruitment start date

2017-01-29, 1395/11/10

Expected recruitment end date

2017-08-23, 1396/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the analgesic effects of one and two miligram bupivacaine added to intrathecal sufentanil on labor analgesia

Public title

Comparison of different doses of bupivacaine in labor spinal analgesia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: ASA 1 primigravid singletone parturients with gestational age (36-40 wk) in active phase of labor (cervix dilation 4-6 cm) Exclusion criteria: Use of analgesic or opioids in recent 12 hours; chronic hypertension; preeclampsia; gestational diabetes; allergy to drugs; cardiovascular disease; coagulopathy

Age

No age limit

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: 40

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

Committee of Ethics in Research, Hamadan University of Medical Sciences

Street address

Hamadan University of Medical Sciences, Shahid Fahmideh Street, Hamedan

City

Hamedan

Postal code

65178

Approval date

2016-10-29, 1395/08/08

Ethics committee reference number

IR.UMSHA.REC.1395.348

Health conditions studied

1

Description of health condition studied

labor analgesia

ICD-10 code

074.9

ICD-10 code description

Complication of anaesthesia during labour and delivery, unspecified

Primary outcomes

1

Description

onset of analgesia

Timepoint

every 5 minutes after spinal injection

Method of measurement

Time from spinal injection until the relief of labor pain in the first 15 min such that the subject did not request rescue medication.(pain VAS<4)

2

Description

duration of analgesia

Timepoint

every 15 minutes after spinal injection

Method of measurement

Time from spinal injection until the end of spinal analgesia.(minute)

Secondary outcomes

1

Description

pruritus

Timepoint

every 15 minutes after spinal injection until the end of spinal analgesia

Method of measurement

VAS for pruritus (0-10)

2

Description

nausea and vomiting

Timepoint

every 15 minutes after spinal injection until the end of spinal analgesia

Method of measurement

yes/no question from patient

3

Description

motor blockade

Timepoint

every 15 minutes after spinal injection

Method of measurement

Bromage Scale (1=no motor block--ability to raise

extended leg against gravity; 2 = inability to raise extended leg, able to bend knee; 3 = inability to bend knee, able to flex ankle; and 4 = complete motor block) were assessed at the 3 levels.

4

Description

Neonatal Apgar score

Timepoint

1 and 5 minutes after birth

Method of measurement

Apgar scale

5

Description

sensory level to cold and pinprick

Timepoint

15 minutes after spinal injection

Method of measurement

question from patient in response to cold and pinprick (dermatomal level)

Intervention groups

1

Description

Intervention 1: Spinal injection consisted 5 microgram □sufentanil with 1 mg of bupivacaine from the L4-L5 or L3-L4 interspace with the patient in the sitting position.

Category

Treatment - Drugs

2

Description

Intervention 2: Spinal injection consisted 5 microgram □sufentanil with 2 mg of bupivacaine from the L4-L5 or L3-L4 interspace with the patient in the sitting position.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Fatemieh hospital

Full name of responsible person

Mahshid Nikooseresht

Street address

Pasdaran Street, Shariati square, Hamadan, Iran

City

Hamadan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for Research and Technology,
Hamadan University Of Medical Sciences

Full name of responsible person

Saiid Bashirian

Street address

Hamadan University of Medical Science, Shahid
Fahmideh street, Hamadan

City

Hamadan

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 and Technology, Hamadan
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

Hamadan University of Medical Sciences

Full name of responsible person

Mahshid Nikooseresht M.D

Position

Assistant Professor of Anesthesiology, Fellowship of
Pain management

Other areas of specialty/work

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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

Person responsible for updating data**Contact****Name of organization / entity**

Hamadan University of Medical Sciences

Full name of responsible person

Mahshid Nikooseresht M.D

Position

Assistant Professor of Anesthesiology, Fellowship of