

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jul 2026

Comparison the effects of spinal anesthesia with bupivacaine versus bupivacaine and fentanyl on sensory and motor block in cervical cerclage operation

Protocol summary

Summary

In this study, we decided to introduce a method of anesthesia for cervical cerclage in parturients which does not produce any side effect on fetus and lead to rapid recovery and early discharge of patient from hospital. This study was accomplished on 30 parturients. Inclusion criteria were pregnant woman; cervical cerclage operation; age 18-40 years old and patients consent. Exclusion criteria were presence of contraindication to spinal anesthesia; allergy to local anesthetic drugs; allergy to narcotics; positive history of analgesic and sedative drugs consumption. The patients were divided randomly to two equal groups by colored cards. Initially 500ml ringer was administered to the patients. Before spinal anesthesia, blood pressure and heart rate were recorded. For spinal anesthesia, patients of one group received 10 mg bupivacaine 0.5% (2ml) and the other group received 5mg bupivacaine 0.5% (1ml) with 10µg fentanyl (0.2 ml) and 0.8 ml normal saline in sitting position. Then in supine position blood pressure and heart rate were measured 2, 4, 6, 8, 10, 15, and 20 minutes after spinal anesthesia and in the recovery room. In the presence of decreased blood pressure to less than 90 mmHg or 20% of baseline level, we administered ephedrine. The time of T10 sensory block establishment and also maximum level of sensory block was determined by pinprick method. We used Bromage score for evaluation of motor block and maximum level of motor block was recorded. At the end of operation, the onset time of ability to movement was recorded. Headache, nausea, vomiting and itching were recorded if they occurred.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201405157695N5**

Registration date: **2014-07-16, 1393/04/25**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2014-07-16, 1393/04/25

Registrant information

Name

Seyedeh Masoumeh Hosseini Valami

Name of organization / entity

Qazvin University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 28 1334 8419

Email address

smhosseini@qums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-Chancellor for research of Qazvin University of Medical Sciences

Expected recruitment start date

2012-08-22, 1391/06/01

Expected recruitment end date

2014-02-20, 1392/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the effects of spinal anesthesia with bupivacaine versus bupivacaine and fentanyl on sensory and motor block in cervical cerclage operation

Public title

Comparison the effects of spinal anesthesia with bupivacaine versus bupivacaine and fentanyl on sensory and motor block in cervical cerclage operation

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria: pregnant woman; cervical cerclage operation; age 18-40 years old; patients consent
Exclusion criteria: presence of contraindication to spinal anesthesia; allergy to local anesthetic drugs; allergy to narcotics; positive history of analgesic drugs consumption; positive history of narcotic and sedative drugs consumption

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **30**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Qazvin University of Medical Sciences

Street address

Shahid Bahaonar Blvd

City

Qazvin

Postal code

Approval date

2012-07-23, 1391/05/02

Ethics committee reference number

28/20/6180

Health conditions studied

1

Description of health condition studied

Cervical incompetency

ICD-10 code

N88.3

ICD-10 code description

Investigation and management of (suspected) cervical incompetence in a nonpregnant woman

Primary outcomes

1

Description

Level of sensory block

Timepoint

Every 2 min

Method of measurement

Pinprick

2

Description

Motor block

Timepoint

Every 2 min

Method of measurement

Bromage score

Secondary outcomes

1

Description

Headache

Timepoint

Continous monitoring

Method of measurement

By questioneer

2

Description

Nausea and vomiting

Timepoint

Continous monitoring

Method of measurement

Visual

3

Description

Itching

Timepoint

Continous monitoring

Method of measurement

Visual

Intervention groups

1

Description

In patients of the first group, 10mg bupivacaine 0.5% (2ml) was injected in subarachnoid space.

Category

Prevention

2

Description

In patients of the second group, 5mg bupivacaine 0.5% (1ml) with 10µg fentanyl (0.2 ml) and 0.8 ml normal saline were injected in subarachnoid space.

Category

Prevention

Recruitment centers

1

Recruitment center

Name of recruitment center

Kosar Hospital

Full name of responsible person

Seyedeh Masoumeh Hosseini Valami M.D.

Street address

Talaghani Blvd, Kosa Alley

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Qazvin

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice-Chancellor for research of Qazvin University of Medical Sciences

Full name of responsible person

Dr. Sayed Assefzadeh

Street address

Qazvin University of Medical Sciences, Shahid Bahonar Blvd

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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

Vice-Chancellor for research of Qazvin 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

Qazvin University of Medical Sciences

Full name of responsible person

Seyedeh Masoumeh Hosseini Valami, M.D.

Position

Anesthesiologist, Associate Professor

Other areas of specialty/work

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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