Clinical Trial Protocol
Iranian Registry of Clinical Trials

18 Sep 2026

Comparison the therapeutic effects of sublingual buprenorphine and fentanyl intravenous pump for controlling pain after cesarean section with spinal

Protocol summary

Summary

Objective: Comparison the therapeutic effects of sublingual buprenorphine and fentanyl intravenous pump for controlling pain after cesarean section with spinal. Design: In this interventional study, 100 women who have criteria for entering the study will be selected and divided into two groups using block randomization method (n=50 in each group). Proper counseling will be done and a written informed consent will be obtained before starting the treatment regimen. Inclusion criteria: Patients with spinal anesthesia during cesarean section. Exclusion criteria: History of drug abuse. Setting and intervention: In the first group, buprenorphine (Faran shimi Co.) will be administered sublingually at a dose of 0.4 mg and Will be repeated at 6 and 12 hours after the first dose. At the same time, 100 cc normal saline will be used intravenously for 24 hours. In the second group, the intravenous fentanyl (Caspian tamin Co.) with a dose of 20 cc per 100 cc of normal saline, will be administered intravenously and continued for up to 24 hours. In this group, sublingual placebo will be used at the start of the intervention and 6, 12 hours after intervention. Outcomes measure: pain score will evaluate according to the VAS score once score at 2, 6, 12, and 24 hours after cesarean section using a structured questionnaire and visual analogue scale. Also The vomiting will be evaluated within 24 hours after the intervention.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2017081723559N14**
Registration date: **2017-08-20, 1396/05/29**
Registration timing: **prospective**

Last update:
Update count: **0**

Registration date

2017-08-20, 1396/05/29

Registrant information

Name

Somaieh Matin

Name of organization / entity

Ardabil University of Medicine Sciences

Country

Iran (Islamic Republic of)

Phone

+98 45 3373 3011

Email address

s.matin@arums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Ardabil University of Medical Sciences

Expected recruitment start date

2017-11-22, 1396/09/01

Expected recruitment end date

2018-03-20, 1396/12/29

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the therapeutic effects of sublingual buprenorphine and fentanyl intravenous pump for controlling pain after cesarean section with spinal

Public title

Comparison of sublingual buprenorphine and intravenous

fentanyl pump for cesarean section pain control

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with spinal anesthesia during cesarean section. Exclusion criteria: History of drug abuse.

Age

No age limit

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **100**

Randomization (investigator's opinion)

N/A

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

Ardabil University of Medicine Sciences Ethics committee

Street address

Ardabil University of Medicine Sciences, Daneshgah street, Ardabil

City

Ardabil

Postal code

Approval date

2017-04-12, 1396/01/23

Ethics committee reference number

IR.ARUMS.REC.1396.2

Health conditions studied

1

Description of health condition studied

caesarean section

ICD-10 code

O82.0

ICD-10 code description

Delivery by elective caesarean section

Primary outcomes

1

Description

pain

Timepoint

Four times (2,6,12and 24 hours) after intervention

Method of measurement

Visual analog scale

Secondary outcomes

1

Description

vomiting

Timepoint

Up to 24 hours after intervention

Method of measurement

Clinical

Intervention groups

1

Description

In the first group, buprenorphine (Faran shimi Co.) will be administered sublingually at a dose of 0.4 mg and Will be repeated at 6 and 12 hours after the first dose. At the same time, 100 cc normal saline will be used intravenously for 24 hours.

Category

Treatment - Drugs

2

Description

In the second group, the intravenous fentanyl (Caspian tamin Co.) with a dose of 20 cc per 100 cc of normal saline, will be administered intravenously and continued for up to 24 hours. In this group, sublingual placebo will be used at the start of the intervention and 6, 12 hours after intervention

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Alavi Hospital

Full name of responsible person

Street address

City

Ardabil

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research, Ardabil University of Medical Sciences
Full name of responsible person
Vice chancellor for research, Ardabil University of Medical Sciences
Street address
Ardabil University of Medical Science, Daneshgah street, Ardabil, Iran
City
Ardabil
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, Ardabil 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
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Person responsible for updating data

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00
Fax
Email
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