Clinical Trial Protocol
Iranian Registry of Clinical Trials

22 Nov 2026

To evaluate the incidence of shivering, analgesic quality and post-operative complications of cesarean section, treated with sputum sufentanil and tramadol

Protocol summary

Study aim
To evaluate the incidence of shivering, analgesic quality and post-operative complications of cesarean section, treated with sputum sufentanil and tramadol

Design
randomized (random block method), double-blind study, without placebo control, single arm trial. The sample size of this study is 135 individuals: divided into 3 groups of 45 people.

Settings and conduct
Amiralmomenin Hospital in Semnan

Participants/Inclusion and exclusion criteria
Women are in the age of 18-40 years old, which candidate for a repeated nonprescription cesarean section at Amiralmomenin Hospital in Semnan. Inclusion Criteria: No Contraindication of Spinal Anesthesia; No history of sensitivity to the three drugs used in this study and other local anesthetics; no neuropathy; no previous history of non-gestational cesarean. Exclusion criteria: women with GI disease; preterm delivery; febrile women (sub-axillary temperature greater than 37.5); preeclampsia; obese women (BMI> 35); cesarean delivery more than 4 times; receiving antiemetic drugs 24 hours before Surgery; Patients with gestational hypertension; Narcotic recipients during surgery; Diabetic; History of PONV; Receiving misoprostol; Patients who cannot perform medication.

Intervention groups
Intervention group 1: Spinal anesthesia with 2.5 cc Bupivacaine 0.5% Intervention group 2: Spinal anesthesia with 2.5 cc bupivacaine 0.5% and 10 mg tramadol. Intervention group 3: Spinal anesthesia with 2.5 cc of bupivacaine 0.5% and 10-5 micrograms (equivalent to 1-2 cc) of sufentanil.

Main outcome variables
Pain relief time, Chill

General information

Reason for update

Acronym

IRCT registration information
IRCT registration number: **IRCT20151228025732N25**
Registration date: **2017-12-20, 1396/09/29**
Registration timing: **retrospective**

Last update: **2017-12-20, 1396/09/29**
Update count: **0**

Registration date
2017-12-20, 1396/09/29

Registrant information

Name
Alireza Emadi

Name of organization / entity
Semnan University of Medical Sciences, Semnan, Iran

Country
Iran (Islamic Republic of)

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+98 23 3345 1336

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are20935@semums.ac.ir

Recruitment status
Recruitment complete

Funding source

Expected recruitment start date
2017-03-21, 1396/01/01

Expected recruitment end date
2017-09-21, 1396/06/30

Actual recruitment start date
empty

Actual recruitment end date
empty

Trial completion date

empty

Scientific title
To evaluate the incidence of shivering, analgesic quality and post-operative complications of cesarean section, treated with sputum sufentanil and tramadol

Public title
To evaluate the incidence of shivering, analgesic quality and post-operative complications of cesarean section, treated with sputum sufentanil and tramadol

Purpose
Treatment

Inclusion/Exclusion criteria

Inclusion criteria:
No Contraindication of Spinal Anesthesia No history of sensitivity to the three drugs used in this study and other local anesthetics no neuropathy no previous history of non-gestational cesarean Women 18 to 40 years

Exclusion criteria:
women with GI disease preterm delivery febrile women (sub-axillary temperature greater than 37.5) preeclampsia obese women (BMI> 35) cesarean delivery more than 4 times receiving antiemetic drugs 24 hours before Surgery Patients with gestational hypertension Narcotic recipients during surgery Diabetic History of PONV Receiving misoprostol Patients who cannot perform medication

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

Gender
Female

Phase
N/A

Groups that have been masked

- Participant
- Investigator
- Outcome assessor

Sample size
Target sample size: **135**

Randomization (investigator's opinion)
Randomized

Randomization description
Randomized (random block method)

Blinding (investigator's opinion)
Double blinded

Blinding description
Injections were performed by the anesthesiologist with spinal cord needle number 25 from lumbar space L4-L5. (The anesthetist and Participate did not know the contents of the syringe).

Placebo
Not used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Ethics committee of Semnan University of Medical Sciences

Street address
Semnan University of Medical Sciences, Basij Blvd, Semnan

City
Semnan

Province
Semnan

Postal code
3514799442

Approval date
2017-02-28, 1395/12/10

Ethics committee reference number
IR.SEMUMS.REC.1395.209

Health conditions studied

1

Description of health condition studied
Complications after cesarean section

ICD-10 code
O34.21

ICD-10 code description
Maternal care for scar from previous cesarean delivery

Primary outcomes

1

Description
Pain relief time

Timepoint
Before and after anesthesia and after delivery (first 20 minutes, every 3 minutes and up to recovery, every 5 minutes), measurements are recorded and recorded.

Method of measurement
Examination

2

Description
Chill

Timepoint
Before and after anesthesia and after delivery (first 20 minutes, every 3 minutes and up to recovery, every 5 minutes), measurements are recorded and recorded.

Method of measurement
See

Secondary outcomes

empty

Intervention groups

1

Description
Intervention group 1: Spinal anesthesia with 2.5 cc Bupivacaine 0.5%
Category
Treatment - Other

2

Description
Intervention group 2: Spinal anesthesia with 2.5 cc bupivacaine 0.5% and 10 mg tramadol.
Category
Treatment - Other

3

Description
Intervention group 3: Spinal anesthesia with 2.5 cc of bupivacaine 0.5% and 10-5 micrograms (equivalent to 1-2 cc) of sufentanil.
Category
Treatment - Other

Recruitment centers

1

Recruitment center
Name of recruitment center
Amiralmomenin Hospital
Full name of responsible person
Elham saffarieh
Street address
Amir Al-Momenin Hospital, Mostafa Khomeini Blvd
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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Mohammadreza Asgari
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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
Semnan University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Semnan University of Medical Sciences
Full name of responsible person
Elham saffarieh
Position
Associate professor
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
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Person responsible for updating data

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Sharing plan

Deidentified Individual Participant Data Set (IPD)
Yes - There is a plan to make this available
Study Protocol
No - There is not a plan to make this available
Statistical Analysis Plan
No - There is not a plan to make this available
Informed Consent Form
No - There is not a plan to make this available
Clinical Study Report
No - There is not a plan to make this available
Analytic Code
No - There is not a plan to make this available
Data Dictionary
No - There is not a plan to make this available
Title and more details about the data/document
-
When the data will become available and for how long
-
To whom data/document is available
Only available to scholars working in academic institutions.
Under which criteria data/document could be used
In case of relevant studies.
From where data/document is obtainable
Elham saffarieh. Amir Al-Momenin Hospital, Mostafa Khomeini Blvd, Semnan. 00989123313982
What processes are involved for a request to access data/document
-
Comments