

Clinical Trial Protocol

Iranian Registry of Clinical Trials

27 Jul 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)

Phone

+98 23 3345 1336

Email address

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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3514799442

Phone

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Email

are20935@gmail.com

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Semnan University of Medical Sciences

Full name of responsible person

Mohammadreza Asgari

Street address

Semnan University of Medical Sciences, Basij Blvd,
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3514799442

Phone

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Email

asgari5000@gmail.com

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

Street address

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

Semnan University of Medical Sciences

Full name of responsible person

Neda Tebyanian

Position

Student

Latest degree

Medical doctor

Other areas of specialty/work

General Practitioner

Street address

Amir Al-Momenin Hospital, Mostafa Khomeini Blvd

City

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Province

Semnan

Postal code