

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jun 2026

Effects of general anesthesia versus spinal anesthesia for cesarean section on acute and chronic post operation pain

Protocol summary

Study aim

Effects of general anesthesia versus spinal anesthesia for cesarean section on acute and chronic post operation pain

Design

Single Blinded Randomized Clinical Trial

Settings and conduct

Intervention group 1: Pregnant women undergo elective cesarean section in group one under general anesthesia. Intervention group 2: Pregnant women undergo elective cesarean section in group 2 undergo spinal anesthesia by 25G spinal needle puncture at the L3-L4 level by injection of 0.5% hyperbaric bupivacaine 10 mg into the intrathecal space.

Participants/Inclusion and exclusion criteria

Inclusion Criteria: Full term pregnant mothers, ASA 1,2, Age over 18 years. Exclusion Criteria: Elective cesarean section, More than two previous cesarean section, Previous abdominal surgery, BMI > 35 kg/m², Chronic inflammatory diseases, Alcohol consumption, Psychiatric diseases, History of chronic pain, Diabetes Mellitus, Preeclampsia and Eclampsia, Coagulation Disorders, Brain tumors, Aspirin use in the last ten days, Infection at the site of the block, Intervertebral Disc, Peripheral neuropathy.

Intervention groups

Intervention group 1: Pregnant women undergo elective cesarean section in group one under general anesthesia. Intervention group 2: Pregnant women undergo elective cesarean section in group 2 undergo spinal anesthesia by 25G spinal needle puncture at the L3-L4 level by injection of 0.5% hyperbaric bupivacaine 10 mg into the intrathecal space.

Main outcome variables

Acute Pain, postoperative analgesic requirement

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141009019470N91**
Registration date: **2019-12-18, 1398/09/27**
Registration timing: **prospective**

Last update: **2019-12-18, 1398/09/27**

Update count: **0**

Registration date

2019-12-18, 1398/09/27

Registrant information

Name

Farzaneh Masihi

Name of organization / entity

Country

Iran (Islamic Republic of)

Phone

+98 71 3647 4270

Email address

masihif@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-01-21, 1398/11/01

Expected recruitment end date

2020-04-20, 1399/02/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Effects of general anesthesia versus spinal anesthesia for cesarean section on acute and chronic post operation pain

Public title

Effects of general anesthesia versus spinal anesthesia for cesarean section on acute and chronic post operation pain

Purpose

Treatment

Inclusion/Exclusion criteria**Inclusion criteria:**

Full term pregnant mothers ASA1,2 Age over 18 years
Elective cesarean section

Exclusion criteria:

More than two previous cesarean section Previous abdominal surgery Obese BMI> 35kg / m2 Chronic inflammatory diseases Alcohol consumption Psychiatric diseases History of chronic pain Diabetes Mellitus Preeclampsia and Eclampsia Coagulation Disorders Brain tumors Aspirin use in the last ten days Infection at the site of the block Intervertebral Disc Peripheral neuropathy

Age

From **18 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor
- Data analyser

Sample size

Target sample size: **128**

Randomization (investigator's opinion)

Randomized

Randomization description

A total of 128 full-term pregnant women undergoing elective cesarean section were randomly assigned to either the spinal (S) or general (G) groups (two groups of 64) using the Randomization.com extracted table.

Blinding (investigator's opinion)

Single blinded

Blinding description

All patients were interviewed by an independent observer (unaware of anesthesia) at 2,4,8,12,18,24 hours postoperatively.

Placebo

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee**

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Vice Chancellor of research, Shiraz University of Medical Sciences, 7th floor, central building of Shiraz University of Medical Sciences, Zand street

City

Shiraz

Province

Fars

Postal code

7134844119

Approval date

empty

Ethics committee reference number

IR.SUMS.MED.REC.1397.188

2**Ethics committee****Name of ethics committee**

Ethics committee of Shiraz University of Medical Sciences

Street address

Vice Chancellor of research, Shiraz University of Medical Sciences, 7th floor, central building of Shiraz University of Medical Sciences, Zand street

City

Shiraz

Province

Fars

Postal code

7134844119

Approval date

2018-08-01, 1397/05/10

Ethics committee reference number

IR.SUMS.MED.REC.1397.188

Health conditions studied**1****Description of health condition studied**

Cesarean delivery

ICD-10 code

P03.4

ICD-10 code description

Newborn (suspected to be) affected by Cesarean delivery

Primary outcomes**1****Description**

Acute Pain

Timepoint

Post-operatively

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

postoperative analgesic requirement -

Timepoint

In the Recovery Room

Method of measurement

Observation

Intervention groups

1

Description

Intervention group: Pregnant women undergo elective cesarean section in group one under general anesthesia.

Category

N/A

2

Description

Intervention group: Pregnant women undergo elective cesarean section in group 2 undergo spinal anesthesia by 25G spinal needle puncture at the L3-L4 level by injection of 0.5% hyperbaric bupivacaine 10 mg into the intrathecal space.

Category

N/A

Recruitment centers

1

Recruitment center

Name of recruitment center

Hafez Hospital

Full name of responsible person

Masoomeh Minoosepehr

Street address

Chamran Boulevard, Hafez Medical Training Center

City

Shiraz

Province

Fars

Postal code

Phone

+98 71 3647 9531

Email

Hafez@sums.ac.ir

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr. Younes Ghasemi

Street address

Vice chancellor of research, 7th floor of central building of Shiraz University of Medical Sciences, Zand street

City

Shiraz

Province

Fars

Postal code

7134844119

Phone

+98 71 3647 4270

Email

sacrc@sums.ac.ir

Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Shiraz 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

Shiraz University of Medical Sciences

Full name of responsible person

Masomeh Minoosepehr

Position

Anesthesiology Resident

Latest degree

Medical doctor

Other areas of specialty/work

Anesthesiology

Street address

Anesthesiology Department, Faghihi Hospital, Zand Street

City

Shiraz

Province

Fars

Postal code

7134844119

Phone

+98 71 3647 4270

Email

asalmspr@gmail.com

Person responsible for scientific inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Saied Khademi

Position

Cardio-anesthesiologist

Latest degree

Subspecialist

Other areas of specialty/work

Anesthesiology

Street address

Anesthesiology Department, Faghihi Hospital, Zand Street

City

Shiraz

Province

Fars

Postal code

7134844119

Phone

+98 71 3647 4270

Email

khademish@sums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Farzaneh Masihi

Position

BS in anesthesia/English Consultant

Latest degree

Master

Other areas of specialty/work

Anesthesiology

Street address

5th floor, Mohammad Rasoul Allah Research Tower, Khalili Street

City

Shiraz

Province

Fars

Postal code

7134844119

Phone

+98 71 3647 4270

Email

masihifarzaneh@yahoo.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be 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