Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 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 group1: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, ASA1,2, Age over 18 years. Exclusion Criteria:Elective cesarean section, More than two previous cesarean section , Previous abdominal surgery, 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.

Intervention groups
Intervention group1: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
Observasion

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 Minosepehr
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