

Clinical Trial Protocol

Iranian Registry of Clinical Trials

29 Jun 2026

Comparison of the duration of analgesia following two method of posterior and lateral transverse abdominal blocks under ultrasound guidance after cesarean section

Protocol summary

Summary

(1)General objective: Comparing the duration of analgesia after posterior and lateral transverse abdominal blocks under ultrasound guidance after cesarean section. (2)Design: No placebo-controlled, one center, randomized, double blind late stage clinical trial (a) all women 18 to 50 years who were referred for elective or emergency cesarean section to general operating room of Rasoul Akram Hospital, Sample size: 76, intervention period:2015-2016. (3)Setting, conduct and Intervention: For all patients undergoing elective cesarean section after spinal anesthesia and analgesia, Monitoring (pulse oximetry, non-invasive measurement of blood pressure and electrocardiogram), and IV line and 500 ml ringer therapy were performed. Spinal anesthesia was done in the sitting position and in sterile conditions with a needle (25 dr japan) and 10 mg of bupivacaine (maylan made in france) for all patients in the operating room. After reaching the T4 level of anesthesia, cesarean section was begun. When systolic blood pressure decreased to less than 80 mm Hg or the drop was more than 30%, 10 mg of ephedrine was injected and in the case of heart rate drop to less than 50 beats per minute, atropine 0.5 mg was injected. After the cesarean and in the recovery room, patients randomly divided into two groups and all patients were monitored (pulse oximetry, non-invasive measurement of blood pressure and electrocardiogram). When the level of spinal anesthesia decreased 2 to 3 levels compared to T4 (The assessment by pin prick and cotton alcohol on the anterior abdomen), 15 cc of bupivacaine 0.25% (Bupivacaine maylan made in france) using a 23 gauge spinal needle (dr japan) was injected in the SUPINE position under the guidance of linear ultrasound probe (Mark SonoSite made in USA) In sterile conditions. In one group lateral TAP block has been done on the midaxillary line in the border of coastal margine and iliac crest

between internal oblique and transverse abdominis the local anaesthetic bilaterally. The other group went under the posterior Tap block (quaderotus lombrum) in the triangular space of petit (the inferior margin of iliac crest and the posterior border of the latissimus dorsi muscle and anterior border external oblique muscle). (4)Participants including major eligibility criteria: Patients were divided to two groups. each group were consist of 38 patients. Inclusion criteria: patients 18 to 50 years old undergoing spinal anesthesia for cesarean section. Exclusion criteria: Patients in the ASA class 3 and more; patients that spinal anesthesia was not successful in them; patients with underlying organic diseases; being allergic to bupivacaine. (5)Main outcome measures: Pain intensity at rest, Pain intensity in coughing situation, opioid need

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2016120431225N1**

Registration date: **2017-03-12, 1395/12/22**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-03-12, 1395/12/22

Registrant information

Name

Maryam Ghaderi Ashtiani

Name of organization / entity

Iran University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 21 2675 4974

Email address

m.ghaderi.ashtiani@gmail.com

Recruitment status

Recruitment complete

Funding source

Investigator.

Expected recruitment start date

2015-12-21, 1394/09/30

Expected recruitment end date

2016-09-22, 1395/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the duration of analgesia following two method of posterior and lateral transverse abdominal blocks under ultrasound guidance after cesarean section

Public title

Transverse muscle block effect in analgesia after cesarean section

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: 18-50 year old females who are candidate for spinal anesthesia for elective and emergency cesarean section due to fetal distress; patients with ASA 1 & 2. Exclusion criteria: patients with ASA>3 & 4; contraindication for the use of spinal anesthesia; Emergent conditions due to organic problems such as eclampsia, preeclampsia, placenta previa and ...; history of allergy to bupivacaine; receiving an analgesic; BMI> 40; pre-pregnancy weight less than 50 kg; patients with an underlying disease or history of renal or liver disease or coagulopathy; prediction of spinal anesthesia unsuccessfulness (including inadequate anesthetic level); patients who have received sedation drugs fentanyl 100 micrograms and midazolam 2 milligrams during the procedure.

Age

From **18 years** old to **50 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **76**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

To create analgesia in the lower abdomen after surgery, there are two main ways that we decided to compare the efficacy of both.

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Iran University of Medical Sciences

Street address

Iran University Of Medical Sciences, Next to Milad tower, Hemmat highway

City

Tehran

Postal code

1449614535

Approval date

2015-12-20, 1394/09/29

Ethics committee reference number

IR.IUMS.REC.1394.9211174015

Health conditions studied

1

Description of health condition studied

acute pain after cesarean section

ICD-10 code

R52.0

ICD-10 code description

Acute pain

Primary outcomes

1

Description

Satisfaction of Analgesia

Timepoint

Immediately after the caesarean section and at 2, 4, 6, 12, 24 and 36 hours after intervention

Method of measurement

Questionnaire

Secondary outcomes

1

Description

Time of first opioid analgesic injection
Timepoint
The first time analgesic request by the patient
Method of measurement
Questionnaire

2

Description
Pain relief score at rest
Timepoint
2, 4, 6, 12, 24, 36 hours after intervention
Method of measurement
Pain Score Questionnaire (zero to ten)

3

Description
Patient satisfaction score
Timepoint
36 hours after intervention
Method of measurement
Questionnaire

4

Description
Nausea and vomiting complaint
Timepoint
2, 4, 6, 12, 24, 36 hours after intervention
Method of measurement
Questionnaire

5

Description
amount of opioid consumption (mg)
Timepoint
36 hours after intervention
Method of measurement
Questionnaire

6

Description
Pain relief score when coughing
Timepoint
2, 4, 6, 12, 24, 36 hours after intervention
Method of measurement
Pain Score Questionnaire (zero to ten)

Intervention groups

1

Description
Intervention group 1: Posterior TAP block (quadratus lumborum) in the triangular space of Petit (iliac crest and the inferior margin of the posterior border of the latissimus dorsi muscle and anterior of external oblique muscle). When the probe was in posterior axillary position (the exact location of the posterior block quadratus lumborum), sono anatomy at the first stage

showed transverse abdominis and then internal and external oblique that were doing aponeurosis. Needle (number 23 dr Japan) was inserted at the junction of abdominal and quadratus lumborum muscles and 15 cc bupivacaine 0.25% (Maylan made in France) was injected bilaterally. The time of injection was immediately after cesarean section and when the anaesthesia had dropped 2 to 3 levels.

Category
Rehabilitation

2

Description
Intervention group 2: lateral tap block was performed through the local injection of 15 cc anesthetic bupivacaine 0.25% using 23 gauge spinal needle (dr Japan) at the junction of midaxillary line and transverse umbilical line (between Coastal margin and iliac crest) between internal oblique and transverse abdominis muscles. The time of injection was immediately after cesarean section and when the anaesthesia had dropped 2 to 3 levels.

Category
Rehabilitation

Recruitment centers

1

Recruitment center
Name of recruitment center
Department of Anesthesiology and Pain, Rasoul Akram Hospital
Full name of responsible person
Maryam Ghaderi Ashtiani (MD), Senior Resident Of Anesthesiology
Street address
Rasool Akram Hospital, Next to Mansouri street, Niayesh street, Sattar Khan street
City
Tehran

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice Chancellor for research of Iran University of Medical Sciences
Full name of responsible person
Maryam Ghaderi Ashtiani (MD)
Street address
Iran University Of Medical Sciences, Next to Milad tower, Hemmat boulevard
City
Tehran
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 of Iran 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
Rasool Akram Hospital
Full name of responsible person
Poupak Rahimzadeh(MD)
Position
Anesthesiologist/Pain Fellowship, Department of Anesthesiology and Pain
Other areas of specialty/work
Street address
Rasool Akram Hospital, Next to Mansouri street, Niayesh street, Sattar khan street
City
Tehran
Postal code
1445613131
Phone
+98 21665173419
Fax
+98 21665173419
Email
Poupak_rah@hotmail.com
Web page address
-

Person responsible for scientific inquiries

Contact

Name of organization / entity
Rasool Akram Hospital
Full name of responsible person
Poupak Rahimzadeh(MD)
Position
Anesthesiologist/Pain Fellowship, Department of Anesthesiology and Pain
Other areas of specialty/work
Street address

Rasool Akram Hospital, Next to Mansouri street, Niayesh street, Sattar khan street

City
Tehran
Postal code
1445613131
Phone
+98 21665173419
Fax
+98 21665173419
Email
Poupak_rah@hotmail.com
Web page address
-

Person responsible for updating data

Contact

Name of organization / entity
Rasool Akram Hospital
Full name of responsible person
Poupak Rahimzade (MD)
Position
Anesthesiologist/Pain Fellowship, Department of Anesthesiology and Pain
Other areas of specialty/work
Street address
Rasool Akram Hospital, Next to Mansouri street, Niayesh street, Sattar khan street
City
Tehran
Postal code
1445613131
Phone
+98 21665173419
Fax
+98 21665173419
Email
Poupak_rah@hotmail.com
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