Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Jun 2026

The opioid sparing effect of adding ultra-low doses of naloxone to bupivacaine% 0/25 with or without sufentanil in Transverse Abdominis Plane Block on patients after elective caesarean section ;double- blind, randomized , clinical trial

Protocol summary

Summary

Transverse abdominis plane block is considered as a method of postoperative pain control in abdominal surgeries. To avoid systemic side effects of analgesics and to reduce the opioid consumption postoperatively we performed TAP block on ceasarean section patients. In this double blind randomised clinical trial ,164 patients candidates for cesarean section, aged between 20-40 ,with ASA Class I,II were randomly assigned to recieve TAP block,in Shariati Hospital during years 2012-2013. After obtaining written consent patients allocated in 4 groups of 41 randomly. After last stitch ,bilateral TAP block was performed under ultrasonographic guide.control group patients recieved 18 ml bupivacaine 0.25% along with 2 cc normal saline on each side, Sufentanil group (S) recieved 18ml bupivaciane 0.25% along with 1ml normal saline and 1ml sufentanil(5micgr)on each side. The Naloxone group (N) recieved 18 ml bupivacaine 0.25% along with 100 (ngr) naloxone (1ml)and 1ml normal saline on each side, and Naloxone and sufentanil group (N+S) recieved 18 ml bupivaciane 0.25% along with sufentanil 1ml(5microgr) and 100 ng naloxone on each side. In the recovery room, pain intensity was measured at baseline then 2h, 6h, 12h, 24h postoperatively using visual analoge scale and the time of first request for analgesic and opioid consumption during 24 h postoperation also wrer recorded . The primary goal was to evaluate the morphine consumption to relief postoperative pain.

General information

Acronym

-

IRCT registration information

IRCT registration number: **IRCT2013041212958N2**

Registration date: **2013-06-07, 1392/03/17**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-06-07, 1392/03/17

Registrant information

Name

Yassaman Aghajani

Name of organization / entity

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Recruitment status

Recruitment complete

Funding source

Tehran University of Medical Sciences

Expected recruitment start date

2012-01-01, 1390/10/11

Expected recruitment end date

2013-02-01, 1391/11/13

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The opioid sparing effect of adding ultra-low doses of

naloxone to bupivacaine% 0/25 with or without sufentanil in Transverse Abdominis Plane Block on patients after elective caesarean section ;double- blind, randomized , clinical trial

Public title
The effect of ultra-low dose of naloxone on analgesia after abdominal wall nerves block in patients after cesarean section
Purpose
Supportive
Inclusion/Exclusion criteria
inclusion criteria: age 20-40; ASA class I,II; primigravid; non addict; without history of allergy to protocol drugs Excluxion criteria: patients whom recieved drugs other than the ones mentioned in protocol in 24 h preoperation; surgery duration more than 90 minutes
Age
From **20 years** old to **40 years** old
Gender
Female

Phase
N/A
Groups that have been masked
No information
Sample size
Target sample size: **164**
Randomization (investigator's opinion)
Randomized
Randomization description
Blinding (investigator's opinion)
Double blinded
Blinding description
Placebo
Used
Assignment
Parallel
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee
Name of ethics committee
Ethics Committee, Faculty of Medicine
Street address
Faculty of Medicine, Tehran University of Medical Sciences and Health Care
City
Tehran
Postal code
-
Approval date
2012-09-26, 1391/07/05
Ethics committee reference number
91/ 130/1409/د

Health conditions studied

1

Description of health condition studied
pain
ICD-10 code
R52.0
ICD-10 code description
acute pain

Primary outcomes

1

Description
Pain intesity
Timepoint
recovery room,2,6,12,24 h after surgery
Method of measurement
visual analoge scale

2

Description
Morphine consumption
Timepoint
recovery room, 2,6,12,24h after surgery
Method of measurement
opioid registration by milligram

Secondary outcomes

1

Description
Sensory Block Duration
Timepoint
24h
Method of measurement
Pinprick test

Intervention groups

1

Description
under guidence of ultrasonography Transverse abdominis Block performed bilateraly in control group "patients recieved 18 ml bupivacaine 0.25% along with 2 cc normal saline on each sideIn the recovery room, pain intensity was measured at baseline then 2h, 6h, 12h, 24h postoperatively using visual analoge scale and the time of first request for analgesic and opioid consumption during 24 h postoperation also wrer recorded .
Category
Treatment - Drugs

2

Description
under guidence of ultrasonography Transverse

abdominis Block performed bilateraly in sufentanil group patients recieved 18 ml bupivacaine 0.25% along with 1 cc normal saline and 1 ml sufentanil (5 microgram) on each sideIn the recovery room, pain intensity was measured at baseline then 2h, 6h, 12h, 24h postoperatively using visual analoge scale and the time of first request for analgesic and opioid consumption during 24 h postoperation also wrer recorded

Category

Treatment - Drugs

3

Description

under guidence of ultrasonography Transverse abdominis Block performed bilateraly in naloxone and sufentanil group patients recieved 18 ml bupivacaine 0.25% along with 1 cc naloxone (100 nanogram) alon with 5 microgram sufentanil on each side In the recovery room, pain intensity was measured at baseline then 2h, 6h, 12h, 24h postoperatively using visual analoge scale and the time of first request for analgesic and opioid consumption during 24 h postoperation also wrer recorded

Category

Treatment - Drugs

4

Description

under guidence of ultrasonography Transverse abdominis Block performed bilateraly in Naloxone group patients recieved 18 ml bupivacaine 0.25% along with 1 cc normal saline alon with 100 nanogram (1 ml) Naloxone on each side In the recovery room, pain intensity was measured at baseline then 2h, 6h, 12h, 24h postoperatively using visual analoge scale and the time of first request for analgesic and opioid consumption during 24 h postoperation also wrer recorded

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dr.Ali Shariati hospital

Full name of responsible person

Samira Sorbi

Street address

Dr.Ali Shariati hospital, North Karegar St.

City

Tehran

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tehran University of Medical Sciences

Full name of responsible person

Shahin Akhoundzade

Street address

Tehran University of Medical Sciences

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Tehran

Grant name

-

Grant code / Reference number

-

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

Yes

Title of funding source

Tehran 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

Tehran University of Medical Sciences

Full name of responsible person

Samira Sorbi

Position

Resident of Anesthesiology

Other areas of specialty/work

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Person responsible for scientific inquiries

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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