

# 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 caesarean section patients. In this double blind randomised clinical trial ,164 patients candidates for caesarean section, aged between 20-40 ,with ASA Class I,II were randomly assigned to receive 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 received 18 ml bupivacaine 0.25% along with 2 cc normal saline on each side, Sufentanil group (S) received 18ml bupivacaine 0.25% along with 1ml normal saline and 1ml sufentanil(5micgr)on each side. The Naloxone group (N) received 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) received 18 ml bupivacaine 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 analogue scale and the time of first request for analgesic and opioid consumption during 24 h postoperation also were 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

Tehran university of medical sciences

###### Country

Iran (Islamic Republic of)

###### Phone

+98 21 8490 2373

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y-aghajani@razi.tums.ac.ir

##### 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  
Exclusion 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/ 130/1409/5

## 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 intensity

#### Timepoint

recovery room,2,6,12,24 h after surgery

#### Method of measurement

visual analogue 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 guidance of ultrasonography Transverse abdominis Block performed bilaterally in control group "patients recieved 18 ml bupivacaine 0.25% along with 2 cc normal saline on each side in the recovery room, pain intensity was measured at baseline then 2h, 6h, 12h, 24h postoperatively using visual analogue scale and the time of first request for analgesic and opioid consumption during 24 h postoperation also were recorded .

#### Category

Treatment - Drugs

### 2

#### Description

under guidance of ultrasonography Transverse

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

#### Category

Treatment - Drugs

### 3

#### Description

under guidance of ultrasonography Transverse abdominis Block performed bilaterally in naloxone and sufentanil group patients received 18 ml bupivacaine 0.25% along with 1 cc naloxone (100 nanogram) along 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 analogue scale and the time of first request for analgesic and opioid consumption during 24 h postoperation also were recorded

#### Category

Treatment - Drugs

### 4

#### Description

under guidance of ultrasonography Transverse abdominis Block performed bilaterally in Naloxone group patients received 18 ml bupivacaine 0.25% along with 1 cc normal saline along 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 analogue scale and the time of first request for analgesic and opioid consumption during 24 h postoperation also were 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

##### City

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

#### Contact

##### Name of organization / entity

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Ali Movafegh

##### Position

Professor

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## Person responsible for updating data

**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**

**Street address**

Dr.Ali Shariati, North Karegar St.

## 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*