

Clinical Trial Protocol

Iranian Registry of Clinical Trials

16 Sep 2026

Pre-incisional Local Infiltration of Tramadol Versus Bupivacaine For Postoperative Pain Control in Elective Cesarean Section surgery

Protocol summary

Summary

In this study we aim to compare the effect of Tramadol Versus Bupivacain in the cesarean section incision painl. and their complications such as: respiratory depression, nausea and vomiting will be compared too. Ninety eight pregnant women in the ASA class I& II, who are candidate for elective cesarean section under general anesthesia will be recruited in this study, they will be allocated randomly according to simple randomization into two groups: 49 patients in the Tramadol group and 49 patients in the Bupivacain group. Patients with history of cardiopulmonary disorders; Allergic reaction to drugs use in study; Alcohol addiction; addiction to opium or other illicit drugs; Chronic pain syndrome; Convulsion will be excluded. In the first group, before surgical incision 20 ml of Bupivacain 0.25% will be injected in the site of incision by surgeon who is not aware of drug used in the study. In the second group, before surgical incision 2mg/Kg Tramadol in total volume of 20 ml of is injected in the site of incision. Then pain intensity of patients will be recorded by educated nurse with visual analogue scale(VAS) in recovery room and ward every one hour till 24 hours and will be compared.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013070111662N2**

Registration date: **2013-09-07, 1392/06/16**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2013-09-07, 1392/06/16

Registrant information

Name

Mohammad Ali Sahmeddini

Name of organization / entity

Shiraz University Of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 71 1231 8072

Email address

sahmeddini@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice-Chancellery of Research and Technology, Shiraz University Of Medical Sciences .

Expected recruitment start date

2013-09-23, 1392/07/01

Expected recruitment end date

2014-03-19, 1392/12/28

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Pre-incisional Local Infiltration of Tramadol Versus Bupivacaine For Postoperative Pain Control in Elective Cesarean Section surgery

Public title

painless effect of the injected tramadol in the Cesarean Section incision

Purpose

Prevention

Inclusion/Exclusion criteria

About 98 females who will candidate for elective cesarean section under general anesthesia wil bel enrolled in this study. Exclusion criteria: Emergency

surgery; Cardiopulmonary disorders; Allergic reaction to drugs use in study; Alcohol addiction; Addiction to opium or other illicit drugs; Chronic pain syndrome; Convulsion.

Age

From **18 years** old to **35 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **49**

Randomization (investigator's opinion)

Randomized

Randomization description

Blinding (investigator's opinion)

Double blinded

Blinding description

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Shiraz University Medical Research Ethic Committee

Street address

Shiraz University of Medical Sciences ,Zand Blv

City

Shiraz

Postal code

197871345

Approval date

2013-04-25, 1392/02/05

Ethics committee reference number

CT-P-92-3976

Health conditions studied

1

Description of health condition studied

Postoperative Pain

ICD-10 code

R10.3

ICD-10 code description

Pain localized to other parts of lower abdomen

Primary outcomes

1

Description

Postoperative pain intensity

Timepoint

Every one hour in the first postoperative 24 hr

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Respiratory depression

Timepoint

Every one hour during first postoperative 24 hr

Method of measurement

Respiratory depression is defined as respiratory rate less than 8 per min

2

Description

Nausea and Vomiting

Timepoint

Every one hour during first postoperative 24 hr

Method of measurement

Nausea is defined as urge to vomiting without ejection of the contents of the stomach through the mouth, Vomiting is defined as to eject of the contents of the stomach through the mouth, usually in a series of involuntary spasmic movements.

Intervention groups

1

Description

In the group A, at the beginning of surgery, before surgical incision 20 ml of bupivacain 0.25% is injected in the site of incision by surgeon who is not aware of drug used in the study.

Category

Treatment - Drugs

2

Description

In the group B, at the beginning of surgery, before surgical incision 2mg/Kg tramadol in total volume of 20 ml of is injected in the site of incision by surgeon who is not aware of drug used in the study.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hafez Training and Medical Center
Full name of responsible person
Mohammad Ali Sahmeddini
Street address
Hafez Training and Medical Center, Chamran Blv
City
Shiraz

+98 71 1647 4270
Email
sahmeddini@sums.ac.ir
Web page address
http://sacrc.sums.ac.ir

Person responsible for scientific inquiries

Contact

Name of organization / entity
Shiraz University of Medical Sciences
Full name of responsible person
Mohammad Ali Sahmeddini
Position
Associate Professor of Anesthesiology
Other areas of specialty/work
Street address
Shiraz Anesthesiology and Critical Care Center,
Namazi Hospital, Namazi Sq
City
Shiraz
Postal code
71937 11351
Phone
+98 71 1647 4270
Fax
+98 71 1647 4270
Email
sahmeddini@sums.ac.ir
Web page address
http://sacrc.sums.ac.ir

Person responsible for updating data

Contact

Name of organization / entity
Shiraz University Of Medical Sciences
Full name of responsible person
MohammadAli Sahmeddini
Position
Associate Professor of Anesthesiology
Other areas of specialty/work
Street address
Namazi Sq, Namazi Hospital, Shiraz
Anesthesiologyand Critical Care Research Center
City
Shiraz
Postal code
7193711351
Phone
+98 71 1647 4270
Fax
+98 71 1647 4270
Email
sahmeddini@sums.ac.ir
Web page address
http://sacrc.sums.ac.ir

Sharing plan

Deidentified Individual Participant Data Set (IPD)

Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice-Chancellery of Research and Technology
Full name of responsible person
Dr.Gholamreza Hatam
Street address
Vice-Chancellery of Research and Technology
Department, 7th floor, Shiraz University Of Medical
Sciences building
City
Shiraz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Vice-Chancellery of Research and Technology
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
Shiraz University Of Medical Sciences
Full name of responsible person
Mohammad Ali Sahmeddini
Position
Associate Professor of Anesthesiology
Other areas of specialty/work
Street address
Shiraz Anesthesiology and Critical Care Center,
Namazi Hospital, Namazi Sq
City
Shiraz
Postal code
71937 11351
Phone
+98 71 1647 4270
Fax

empty
Study Protocol
empty
Statistical Analysis Plan
empty
Informed Consent Form
empty

Clinical Study Report
empty
Analytic Code
empty
Data Dictionary
empty