Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jun 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

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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 Anlouge 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 ofof the contents of the stomach through the mouth, Vomiting is defined asto 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 begining 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 begining 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

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Shiraz

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
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Full name of responsible person
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Position
Associate Professor of Anesthesiology

Other areas of specialty/work

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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