

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

Comparison of postoperative analgesic effect of tramadol with bupivacaine for cesarean section

Protocol summary

Summary

In this trial, we compare analgesic anesthetic and effect of tramadol and lidocaine for cesarean section. 60 patients with complete healthy condition; 1st and 2nd elective cesarean section; age between 18-45; without sensitivity to study drugs and opium addiction included the study. In group 1, surgeon will infiltrate bupivacaine 2 mg/kg subcutaneously immediately after cesarean. In group 2, surgeon will infiltrate tramadol 2 mg/kg subcutaneously immediately after cesarean. We assessed postoperative pain, 1,2,3 hours after cesarean using visual analogue scale.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201106203468N8**
Registration date: **2011-09-22, 1390/06/31**
Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2011-09-22, 1390/06/31

Registrant information

Name

Mohammad Reza Hajiesmaeili

Name of organization / entity

Tehran University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

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Recruitment status

Recruitment complete

Funding source

Pain Research Center, Shahid Sadoughi University of Medical Science and Health Services, Yazd, Iran

Expected recruitment start date

1990-02-01, 1368/11/12

Expected recruitment end date

2011-12-21, 1390/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of postoperative analgesic effect of tramadol with bupivacaine for cesarean section

Public title

Postoperative analgesic effect of tramadol and bupivacaine for cesarean section

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria: complete health condition; first or second time elective cesarean section candidate; age between 18-45 years. Exclusion criteria: sensitivity to study drugs; opium addiction

Age

From **18 years** old to **45 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **60**

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

Shahid Sadoughi University of Medical Science and Health Services

Street address

Shahid Bahonar Squire-Yazd-Iran

City

Yazd

Postal code

8919895746

Approval date

2011-08-03, 1390/05/12

Ethics committee reference number

17/1/57202/پ

Health conditions studied

1

Description of health condition studied

cesarean section

ICD-10 code

O82.0

ICD-10 code description

Delivery by elective caesarean section

Primary outcomes

1

Description

postoperative pain

Timepoint

1,2,3 hours after cesarean

Method of measurement

visual analogue scale

2

Description

time to first analgesic request

Timepoint

time between intervention and first analgesic

administratin
Method of measurement
minutes

3

Description

total analgesic consumption

Timepoint

24 after intervention

Method of measurement

mg/kg consumed meperidine

Secondary outcomes

1

Description

side effects

Timepoint

24 hours after intervention

Method of measurement

observation

Intervention groups

1

Description

in group 1, surgeon will infiltrate bupivacaine 2 mg/kg subcutaneously immediately after cesarean.

Category

Other

2

Description

in group 2, surgeon will infiltrate tramadol 2 mg/kg subcutaneously immediately after cesarean.

Category

Other

Recruitment centers

1

Recruitment center

Name of recruitment center

Ayatollah Khatami Hospital

Full name of responsible person

Dr Atiyeh Gavaheri

Street address

City

Herat

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Pain Research Center
Full name of responsible person
Dr Shekoufeh Behdad
Street address
Shahid Sadoughi Hospital, Yazd, Iran
City
Yazd
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Pain Research Center
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
Ayatollah Khatami Hospital
Full name of responsible person
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Person responsible for scientific inquiries

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Person responsible for updating data

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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