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 trail, we compare analgesic anesthetic and effect of tramadol and lidicaine 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 subcutaneusely immediately after cesarean. in group 2, surgeon will infiltrate tramadol 2 mg/kg subcutaneusely immediately after cesarean. We assessed postoperative pain, 1,2,3 hours after cesareanusing 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
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Tehran University of Medical Sciences
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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 consumped 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 subcutaneusely immediately after cesarean.
Category
Other

2

Description
in group 2, surgeon will infiltrate tramadol 2 mg/kg subcutaneusely 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
Dr Atiyeh Gavaheri

Position
Gynecologist

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