Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Comparison of postoperative analgesic effect of subcutaneous administration of tramadol or bupivacaine in the incision of cesarean section.

Protocol summary

Summary

The purpose of this study was to evaluate the effects of tramadol vs bupivacaine administration at wound closure on postoperative pain relief in patients undergoing cesarean section (CS). Sixty women undergoing cesarean deliveries were randomly assigned to receive either 10ml of bupivacaine 0.5% (n=30) or 50mg tramadol in 10ml normal saline (n=30) both as a local wound infiltration prior to skin closure at the end of operation. Postoperative pain is evaluated with a visual analogue scale (VAS: 0-10) at 1, 2 and 6 hours after operation. Time to first analgesic administration, analgesic consumption in the 24hours after operation is recorded and compared in two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201204132963N9**
Registration date: **2012-04-18, 1391/01/30**
Registration timing: **retrospective**

Last update:
Update count: **0**

Registration date

2012-04-18, 1391/01/30

Registrant information

Name
Shekoufeh Behdad
Name of organization / entity
Shahid Sadoughi University of Medical Sciences
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Iran (Islamic Republic of)
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+98 35 1822 1386
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Recruitment status

Recruitment complete

Funding source
Shahid Sadoughi University of Medical Sciences

Expected recruitment start date

2011-04-14, 1390/01/25

Expected recruitment end date

2012-03-15, 1390/12/25

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of postoperative analgesic effect of subcutaneous administration of tramadol or bupivacaine in the incision of cesarean section.

Public title

Comparison of postoperative analgesic effect of subcutaneous administration of two drugs in the incision of cesarean section.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria :patients with term pregnancy and normal fetus ,in range of 18-35yr,60-90kg,and no underline disease who are candidate for cesarean section. Exclusion criteria:cardio-pulmonary disease, diabetes, hypertention, preeclampsia, previous history of addiction.

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: **60**
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
Shahid Sadoughi University of Medical Sciences
Street address
Bahonar square
City
Yazd
Postal code
Approval date
2011-04-12, 1390/01/23
Ethics committee reference number
38523

Health conditions studied

1

Description of health condition studied
postoperative abdominal pain
ICD-10 code
R10.3
ICD-10 code description
Pain localized to other parts of lower abdomen

Primary outcomes

1

Description
postoperative pain
Timepoint
1,2 and 6 hours postoperatively
Method of measurement
visual analog pain score

Secondary outcomes

1

Description
the first request of the patient for analgesic
Timepoint
during 24 hours after operation
Method of measurement
in hours

2

Description
opioid consumption
Timepoint
during 24 hours after operation
Method of measurement
mg morphine

3

Description
Drug side effects
Timepoint
during 24 hours after the operation
Method of measurement
asking the patient

Intervention groups

1

Description
subcutaneous administration of 10ml of bupivacaine 0.5% as a local wound infiltration prior to skin closure at the end of operation
Category
Treatment - Drugs

2

Description
subcutaneous administration of 50mg tramadol in 10ml normal saline as a local wound infiltration prior to skin closure at the end of operation
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Shahid Sadoughi Hospital
Full name of responsible person
Dr.Shekoufeh Behdad
Street address
Shahid Sadoughi Hospital
City
Yazd

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahid Sadoughi University of Medical Sciences
Full name of responsible person
Dr. Hasan Mozaffari
Street address
Bahonar square
City
Yazd
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahid Sadoughi 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
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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