

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 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

Country

Iran (Islamic Republic of)

Phone

+98 35 1822 1386

Email address

drbehdad@ssu.ac.ir

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, hypertension, 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

Name of organization / entity

Shahid Sadoughi University of Medical Sciences

Full name of responsible person

Shekoufeh Behdad

Position

Assistant of professor

Other areas of specialty/work

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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