

Clinical Trial Protocol

Iranian Registry of Clinical Trials

07 Jul 2026

The effect of intra abdominal infiltration with bupivacaine in reducing postoperative diclofenac need in elective cesarean sections.

Protocol summary

Summary

The aim of this study is to determine the effect of intra abdominal wall infiltration with bupivacaine to reduce post operative diclofenac need in elective cesarean sections. Inclusion criteria were: women with first single term pregnancy who are candidate for elective caesarean section, spinal anaesthesia, BMI between 20 to 25 before pregnancy, and time of surgery less than 40 minutes. Exclusion criteria were: bleeding, atonia or any unpredicted accident during or after surgery. fannenstiel incision, opium consumption, underlying disease, history of previous abdominal surgery, sensitivity to amid drugs. In this double- blind, placebo-controlled trial, 60 healthy women with single term pregnancy, after obtaining written informed consent, were randomized into two groups. Patients underwent spinal anesthesia, and then they received a combination of 30cc of 0.25% bupivacaine with 1.5cc of 1:200000 epinephrine as intra abdominal wall infiltration or equal volume of saline in cesarean section at the time of abdominal closure. Pain was assessed using a visual analogue scale 1, 2, 3, 4, 8 and 12 h after the operation. Also mean diclofenac consumption was assessed during 12 h after the operation. The final analysis was done with statistical tests including Chi Square, Non Parametric test and Mann-withny U by SPSS ($P < 0.05$ was considered significant). Mean pain scores after the operation and mean diclofenac consumption in 12 h were compred between two groups. Also the time we prescribed diclofenac was compared between two groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT138812243574N1**

Registration date: **2010-05-29, 1389/03/08**

Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2010-05-29, 1389/03/08

Registrant information

Name

Nader Esmalipour

Name of organization / entity

Guilan University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Research vice chancellorship -Guilan university of medical sciences

Expected recruitment start date

2008-12-28, 1387/10/08

Expected recruitment end date

2009-09-17, 1388/06/26

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The effect of intra abdominal infiltration with bupivacaine in reducing postoperative diclofenac need in elective cesarean sections.

Public title

The effect of intra abdominal infiltration with bupivacaine in reducing postoperative diclofenac need in elective

cesarean sections.

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria were: women with first single term pregnancy who are candidate for elective caesarean section, spinal anaesthesia, BMI between 20 to 25 before pregnancy, and time of surgery less than 40 minutes.

Exclusion criteria were: bleeding, atonia or any unpredicted accident during or after surgery. fannenstiel incision, opium consumption, underlying disease, history of previous abdominal surgery, sensitivity to amid drugs

Age

From **16 years** old to **39 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

Research vice chancellorship-Guilan university of medical sciences

Street address

Namjo st., Research vice chancellorship, Guilan university of medical sciences

City

Rasht

Postal code

Approval date

2009-10-11, 1388/07/19

Ethics committee reference number

4186

Health conditions studied

1

Description of health condition studied

Delivery by elective caesarean section

ICD-10 code

O82.0

ICD-10 code description

Delivery by elective caesarean section

Primary outcomes

1

Description

Pain Severity

Timepoint

1, 2, 3, 4, 8, and 12 hours after operation

Method of measurement

Visual analogue scale

Secondary outcomes

1

Description

Duration of painless period

Timepoint

1, 2, 3, 4, 8, and 12 hours after operation

Method of measurement

The time span between the end of the operation and the time we prescribed first dose of diclofenac

2

Description

Diclofenac use after operation

Timepoint

Over 12 hours

Method of measurement

Total diclofenac consumption

Intervention groups

1

Description

intra abdominal wall infiltration of 30 cc of 0.25% bupivacaine

Category

Treatment - Drugs

2

Description

intra abdominal wall infiltration of 30 cc normal saline

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Guilan university of medical sciences, Alzahra Hospital

Full name of responsible person

Street address

City

Rasht

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Research vice chancellorship, Guilan university of medical sciences

Full name of responsible person

Dr Abdolrasol Sobhani

Street address

Namjo st., Research vice chancellorship, Guilan university of medical sciences

City

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Research vice chancellorship, Guilan 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

Guilan university of medical sciences

Full name of responsible person

Dr Nader Esmailpour

Position

Assistant Professor of Obstetric and Gynecology, Guilan university of Medical Sciences

Other areas of specialty/work

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Person responsible for updating data

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Name of organization / entity

Reproductive Health Research center

Full name of responsible person

Seyede Fatemeh Dalil Hirati

Position

Bs in Midwifery

Other areas of specialty/work

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Reproductive Health Research center, Alzahra hospital, Namjo st.,

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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