

Clinical Trial Protocol

Iranian Registry of Clinical Trials

31 May 2026

The comparison of the effect of intravenous acetaminophen with diclofenac suppository and incisional bupivacain combination on the first 24hour postoperative pain after cesarian section

Protocol summary

Summary

The aim of this study is to compare the effect of intravenous acetaminophen with combination of suppository diclofenac and incisional bupivacaine on post cesarean section pain control. This will be an interventional, double-blinded, single center, controlled with placebo and randomized study on 100 pregnant women candidates of elective cesarean section, 18 to 45 years of age. Emergency cases, individuals with history of opioid addiction, severe cardiac, renal and hepatic disorders, gastro-esophageal reflux disease and convulsion will be excluded. Patients will randomly allocated to either intravenous acetaminophen (A) or combination of incisional bupivacaine and diclofenac (B) group. The patients of both groups will undergo general anesthesia in a similar manner. On arrival to recovery room group A patients will receive 20 mg/kg intravenous acetaminophen in 100 ml normal saline and the patients in group B just the same volume of normal saline. Group B patients will receive a diclofenac suppository (50 mg) before surgery and another two doses within 8 hr intervals and in group A the patients will take placebo suppositories at the same intervals. At the end of the procedure the patients in B group will have 1.5 mg/kg intraincisional injections of 0.25% bupivacaine and the other group 0.6 ml/kg (same volume) of normal saline injection. All the placebo compounds will be prepared with similar appearances to their drug counterparts and neither patients nor prescribers or data assessing personels will be aware of their true nature. Postoperative pain will be treated by intravenous morphine injections. Pain as the primary outcome will be assessed by NRS at 6, 12, 18 and 24 hours after surgery. Secondary outcomes include: assessment of the time of first request for analgesic, 24 hr morphine consumption, patient's sleep, sedation score (by Wilson criteria), drug side effects (nausea and vomiting and pruritus), pain

intensity during ambulation and global satisfaction of the patients.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201501223213N3**

Registration date: **2015-03-01, 1393/12/10**

Registration timing: **registered_while_recruiting**

Last update:

Update count: **0**

Registration date

2015-03-01, 1393/12/10

Registrant information

Name

Arash Farbood

Name of organization / entity

Shiraz University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 71 1233 7636

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Recruitment status

Recruitment complete

Funding source

Shiraz University of Medical Sciences

Expected recruitment start date

2015-02-01, 1393/11/12

Expected recruitment end date

2015-06-21, 1394/03/31

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The comparison of the effect of intravenous acetaminophen with diclofenac suppository and incisional bupivacain combination on the first 24hour postoperative pain after cesarian section

Public title

Comparison of the effect of acetaminophen with combination of diclofenac and incisional bupivacaine in controlling pain after Cesarean section

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: full-term pregnant women candidate for elective cesarean section; age: 18 to 45 years;ASA class1 and 2; between 50 to 80kg weight Exclusion criteria : strong indication for spinal anesthesia; emergency cesarean section; opioid addiction; anxiety and depressive disorders; gastro-esophageal reflux disease; severe renal disease; heart disease liver disease; seizure disease; positive history of hypersensitivity to the drugs used in the study; analgesic consumption in the last 24 hr; non-cooperative patients

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: **100**

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**

Shiraz University of Medical Sciences

Street address

Shiraz University of Medical Sciences, Zand Boulevard

City

Shiraz

Postal code**Approval date**

2014-11-16, 1393/08/25

Ethics committee reference number

Ct-2014-247

Health conditions studied**1****Description of health condition studied**

Pain after cesarian section

ICD-10 code

O82.9

ICD-10 code description

Delivery by cesarean section, unspecified

Primary outcomes**1****Description**

Pain

Timepoint

Every 6 hr in the first 24 hr after cesarian section

Method of measurement

NRS score

Secondary outcomes**1****Description**

24 hr morphine consumption

Timepoint

Once, 24 hr after operation

Method of measurement

Total dose of morphine administered (mg)

2**Description**

Time to first request for analgesic after operation

Timepoint

Once after the procedure

Method of measurement

Time interval from the end of the surgery to the first patient's request for analgesic (minute)

3**Description**

Patient's sleep

Timepoint

Next morning after operation

Method of measurement

3 point scale: 1: good - 2: interrupted - 3: no sleep

4

Description

Sedation score

Timepoint

Every 6 hr after operation till 24 hr

Method of measurement

Wilson scale

5

Description

Pain intensity at ambulation

Timepoint

Once during ambulation

Method of measurement

NRS

6

Description

Drug side effects: nausea and vomiting

Timepoint

Every 6 hr after operation till 24 hr

Method of measurement

3 points scale: 1: non, 2: nausea, 3: nausea and vomiting

7

Description

Patients satisfaction of pain control

Timepoint

Once, 24 hr after operation

Method of measurement

11 points NRS (0: extremely dissatisfied, 5: neutral, and 10: most satisfied)

8

Description

Drug side effects: pruritus

Timepoint

Every 6 hr till 24 hr after operation

Method of measurement

11 points NRS

Intervention groups

1

Description

Before starting surgery patients in group A (acetaminophen) will receive a suppository placebo and then two other doses, all 8 hr apart. At the end of the procedure a 0.6 ml/kg normal saline (as placebo) will be injected in their incision area. On arrival to recovery room 15 mg/kg acetaminophen in 100 ml normal saline will be administered, intravenously and this will be repeated two more times, 8 hours apart.

Category

Treatment - Drugs

2

Description

Before starting surgery patients in group B (diclofenac + bupivacaine) will receive a suppository diclofenac (50 mg) and then two other doses, all 8 hr apart. At the end of the procedure 1.5 mg/kg bupivacaine 0.25% will be injected in their incision area. On arrival to recovery room 100 ml normal saline will be administered, intravenously.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Dena Hospital

Full name of responsible person

Solmaz Heidari

Street address

Zargari Boulevard

City

Shiraz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Kazem Samadi

Street address

Shiraz University of Medical Sciences, Zand Boulevard

City

Shiraz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Shiraz 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
Shiraz University of Medical Sciences

Full name of responsible person
Arash Farbood

Position
Anesthesiologist/Assistant Professor

Other areas of specialty/work

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Email

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