Clinical Trial Protocol
Iranian Registry of Clinical Trials

08 Nov 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
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Name of organization / entity
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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 an 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) an 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
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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