

Clinical Trial Protocol

Iranian Registry of Clinical Trials

18 Sep 2026

Comparison of the effect of Intravenous tramadol with Dexamethasone and tramadol with diclofenac on acute post-operative pain after cesarean surgery

Protocol summary

Summary

After obtaining written informed consent from eligible patients, and getting an approval from Ethics committee of Ahvaz Jundishapur University of Medical Sciences, a double-blind prospective, randomized study will be done among patients with Elective Cesarean Section. Spinal anesthesia with 12.5 mg Marcaine will do in both groups equally. Inclusion criteria: - The patient's satisfaction - Age between 18 and 30 years old - ASA class I & II. Exclusion criteria: - The lack of patient's satisfaction to spinal anesthesia - History of hypnotics or narcotics throughout 24 hours before the surgery - History of drug abuse, or alcohol dependency -Contraindications of Spinal Anesthesia (Patient refusal; Infection at the site of planned needle puncture; Elevated intracranial pressure and Bleeding diathesis). Patients will be randomly allocated into two groups according to table of random numbers. Groups "one", and "two" will receive 100 mg of Teramadol with 8 mg Dexamethasone After end of surgery intravenously, 100 mg of Teramadol intravenously with 75 mg Diclofenac intramuscularly after end of surgery, respectively. Postoperative pain and needs for analgesics will measure at 2, 4, 8,12,8 and 24 hours after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2014070718392N1**

Registration date: **2014-07-19, 1393/04/28**

Registration timing: **prospective**

Last update:

Update count: **0**

Registration date

2014-07-19, 1393/04/28

Registrant information

Name

Shaghayegh Mousavian

Name of organization / entity

Ahvaz Jundishapur University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 61 1222 0168

Email address

mousavian.sh@ajums.ac.ir

Recruitment status

Recruitment complete

Funding source

Vice chancellor for research, Ahvaz University of Medical Sciences

Expected recruitment start date

2014-10-23, 1393/08/01

Expected recruitment end date

2015-03-06, 1393/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the effect of Intravenous tramadol with Dexamethasone and tramadol with diclofenac on acute post-operative pain after cesarean surgery

Public title

Comparison of the effect of Intravenous tramadol with Dexamethasone and tramadol with diclofenac on acute post-operative pain after cesarean surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: - The patient's satisfaction - Age between 18 and 30 years old - ASA class I & II Exclusion criteria: - The lack of patient's satisfaction to spinal anesthesia - History of hypnotics or narcotics throughout 24 hours before the surgery - History of drug abuse, or alcohol dependency - Contraindications of Spinal Anesthesia(Patient refusal ; Infection at the site of planned needle puncture ; Elevated intracranial pressure and Bleeding diathesis)

Age

From **18 years** old to **30 years** old

Gender

Female

Phase

2-3

Groups that have been masked

No information

Sample size

Target sample size: **80**

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

Ethics Committee of Ahvaz Jundishapur University of Medical Sciences

Street address

No. 21, Ave. 1, Golestan Blvd.

City

Ahvaz

Postal code

6135733777

Approval date

2014-01-11, 1392/10/21

Ethics committee reference number

Ajums.REC.1392.241

Health conditions studied

1

Description of health condition studied

Pain

ICD-10 code

R52.0

ICD-10 code description

Acute Pain

Primary outcomes

1

Description

Pain

Timepoint

2,4,8,12 and 24 hours after surgery

Method of measurement

Visual Analogue Scale

Secondary outcomes

1

Description

Opioid Consumption

Timepoint

24 hours after surgery

Method of measurement

Milligram

Intervention groups

1

Description

Drugs: 1-Teramadol: Dose: 100 mg Number of using: Once Factory name: Alborz Darou Manufacturing Country's Name: Iran Location prescribed: Intravenous Administration time: After end of surgery 2- Dexamethasone: Dose: 8 mg Number of using: Once Factory name: Daroupakhsh Manufacturing Country's Name: Iran Location prescribed: Intravenous Administration time: After end of surgery

Category

Treatment - Drugs

2

Description

Drugs: 1-Teramadol: Dose: 100 mg Number of using: Once Factory name: Alborz Darou Manufacturing Country's Name: Iran Location prescribed: Intravenous Administration time: After end of surgery 2- Diclofenac: Dose: 75 mg Number of using: Once Factory name: Daroupakhsh Manufacturing Country's Name: Iran Location prescribed: Intramuscular Administration time: After end of surgery

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Educational Hospital

Full name of responsible person

Dr. Kaveh Behaeen

Street address

No. 307, Kokab Street, Masters Alley, Golestan Blvd.

City

Ahvaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice chancellor for research, Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Dr. Mostafa Fegghi

Street address

No. 21, Ave. 1, Golestan Blvd.

City

Ahvaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Vice chancellor for research, Ahvaz Jundishapur 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

Ahvaz Jundishapur University of Medical Sciences

Full name of responsible person

Shaghayegh Mousavian

Position

Resident of Anesthesia

Other areas of specialty/work

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Person responsible for updating data

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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