

Clinical Trial Protocol

Iranian Registry of Clinical Trials

10 Jun 2026

A comparison of the effects of diclofenac sodium suppositories, intravenous paracetamol and the combination of diclofenac sodium suppositories and intravenous paracetamol on reducing the acute pain and the need to narcotic pain relievers after cesarean surgery under spinal anesthesia

Protocol summary

Summary

Aim of the study: A comparison of the effects of diclofenac sodium suppositories, intravenous paracetamol and the combination of diclofenac sodium suppositories and intravenous paracetamol on reducing the acute pain and the need to narcotic pain relievers after cesarean surgery under spinal anesthesia Study design: Randomized double-blind Study population: Patients candidate for cesarean surgery Sample size: 99 patients Intervention or study interventions: 1. diclofenac sodium suppositories 2. intravenous paracetamol 3. combination of diclofenac sodium suppositories and intravenous paracetamol Intervention period: 21/4/2013 Consequence of study: Given the importance of reducing the side effects of narcotic pain relievers after surgeries and given the importance of reducing pain in the patient, it is necessary to study auxiliary methods for reducing the dose of narcotic drugs and to replacing them, this study aimed to investigate the effect of intravenous paracetamol and the diclofenac sodium suppositories in decreasing the morphine use. If using intravenous paracetamol and the diclofenac sodium suppositories yield positive consequences for the patients, they can replace the narcotic pain relievers.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013022512593N1**
Registration date: **2013-12-04, 1392/09/13**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2013-12-04, 1392/09/13

Registrant information

Name

GholamReza Safari HezarVand

Name of organization / entity

Ahvaz Jondishapour University of Medical Sciences

Country

Iran (Islamic Republic of)

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+98 61 1222 2118

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Recruitment status

Recruitment complete

Funding source

Ahvaz Jundishapur University of Medical Sciences (AJUMS)

Expected recruitment start date

2013-04-21, 1392/02/01

Expected recruitment end date

2013-08-23, 1392/06/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

A comparison of the effects of diclofenac sodium suppositories, intravenous paracetamol and the combination of diclofenac sodium suppositories and

intravenous paracetamol on reducing the acute pain and the need to narcotic pain relievers after cesarean surgery under spinal anesthesia

Public title

Reducing the acute pain and the need to narcotic pain relievers after cesarean surgery

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Being in ASA class 1 or 2; Being in ages between 18-35; Being first or second pregnancy.

Exclusion criteria: Having any known allergies and sensitivities, banned from narcotic drugs, paracetamol, and NSAIDs; Hepatic Dysfunction (transaminase twice than upper limit of normal level); Kidney dysfunction (plasma creatinine higher than 2.5 mg/dl); Smoking or having any previous pulmonary disease; Drug, narcotic, and alcohol abuse; Subjects with the history of depression or chronic anxiety; Subjects experienced the side effects of spinal anesthesia: back pain, radicular pain, paresthesia and hypoesthesia, PDPH; Spinal contraindication; Contraindications for the Use of Spinal Anesthesia (Patient decline, infection in the spot for entering the needle, high intracranial pressure, bleeding susceptibility).

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: **99**

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

morality in research committee

Street address

Ahvaz Jondishapur University of medical Sciences

City

Ahvaz

Postal code

Approval date

2013-09-28, 1392/07/06

Ethics committee reference number

ajums.REC.1392.127

Health conditions studied

1

Description of health condition studied

cesarean surgery

ICD-10 code

O32

ICD-10 code description

Maternal care for known or suspected malpresentation of fetus

Primary outcomes

1

Description

patient reported pain level

Timepoint

1, 4, 12, and 24 hours after surgery

Method of measurement

Visual Analog Scale for Pain (VAS Pain)

Secondary outcomes

1

Description

Intravenous Morphine

Timepoint

in periods of 0-4; 4-12; and 12-24 hours after surgery

Method of measurement

intravenous morphine dose (mg/kg)

Intervention groups

1

Description

Second group will receive 1 gr intravenous paracetamol in 500 cc normal saline while entering the recovery and then they will receive 3gr intravenous paracetamol via PCA pump plus one placebo suppository while leaving the recovery room.

Category

Treatment - Drugs

2

Description

First group will receive 100 mg Diclofenac sodium suppositories when entering the recovery and then they will receive 100 cc Normal saline via PCA pump.

Category

Treatment - Drugs

3

Description

Third group will receive 1 gr intravenous paracetamol in 500 cc normal saline while entering the recovery and then they will receive 3gr intravenous paracetamol via PCA pomp plus a diclofenac 100 mg suppository

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Imam Khomeini Hospital of Ahwaz

Full name of responsible person

Dr. Reza Safari Hezarvand

Street address

postal code: 6193673166; Azadegan Steet, Imam Khomeini Hospital of Ahwaz

City

Ahwaz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Ahwaz Jundishapur University of Medical Sciences (AJUMS)

Full name of responsible person

Dr. Mostafa Fegghi

Street address

Golestan Boulevard, University Prdise

City

Ahwaz

Grant name

Grant code / Reference number

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

Yes

Title of funding source

Ahwaz Jundishapur University of Medical Sciences (AJUMS)

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

Ahwaz Jundishapur University of Medical Sciences (AJUMS)

Full name of responsible person

Dr. Gholamreza Safari Hezarvand

Position

anesthesiology residency

Other areas of specialty/work

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Position

General Practitioner

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