Clinical Trial Protocol
Iranian Registry of Clinical Trials

16 Sep 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)

Phone

+98 61 1222 2118

Email address

safari.r@ajums.ac.ir

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 (transaminaze 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 surgey
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 pomp 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 pomp.
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
Ahvaz

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences (AJUMS)
Full name of responsible person
Dr. Mostafa Feghhi
Street address
Golestan Bulevard, University Prdise
City
Ahvaz
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Ahvaz 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
Ahvaz Jundishapur University of Medical Sciences (AJUMS)
Full name of responsible person
Dr. Gholamreza Safari Hezarvand
Position
anesthesiology residency
Other areas of specialty/work
Street address
Golestan bulevard, University Pardise,
City
Ahvaz
Postal code
Phone
+98 61 1332 3175
Fax
Email
safari.r@ajums.ac.irreza.safari79@gmail.com
Web page address

Person responsible for scientific inquiries

Contact
Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences
Full name of responsible person
Dr. Gholamreza Safari Hezarvand
Position
General Practitioner
Other areas of specialty/work
Street address
Golestan bulevard, unevrsity pardis,
City
Ahvaz
Postal code
Phone
+98 61 1332 3175
Fax
Email
safari.r@ajums.ac.irreza.safari79@gmail.com
Web page address

Person responsible for updating data

Contact
Name of organization / entity
Ahvaz Jundishapur University of Medical Sciences (AJUMS)
Full name of responsible person
Dr. Gholamreza Safari Hezarvan
Position
general practitioner
Other areas of specialty/work
Street address
Golestan bulevard, Unversity Pardise
City
Ahvaz
Postal code

Phone
+98 61 1332 3175
Fax
Email
reza.safari79@gmail.comsafari.r@ajums.ac.ir
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