

Clinical Trial Protocol

Iranian Registry of Clinical Trials

04 Jul 2026

Comparison the Analgesic Effects of Acetaminophen, Meperidine, and their Combination on Postoperative Pain Management in Elective Cesarean Section Surgeries under Spinal Anesthesia

Protocol summary

Study aim

Comparison the analgesic Effects of Acetaminophen, Meperidine, and Their Combination on Postoperative Pain Management in Elective Cesarean Section Surgeries under spinal anesthesia

Design

randomized double-blind, parallel-group

Settings and conduct

The patients were randomly allocated to three groups as follows: Group one:40 patients received 15mg/kg iv. acetaminophen (diluted in 100 cc normal saline solution), Group two:40 patients received 0.5mg/kg iv meperidine Group three:40 patients received 15mg/kg iv. acetaminophen + 0.5mg/kg meperidine within 15 minutes in the Hafez Hospital, Shiraz,

Participants/Inclusion and exclusion criteria

Inclusion criteria:120 full-term pregnant women aged 18 to 40 years old with ASA I, undergoing elective cesarean section under spinal anesthesia. Exclusion criteria: contraindications for meperidine or acetaminophen, history of alcoholism, drug abuse, convulsion, migraine, dicopathy, hepatitis, renal failure, cardiovascular or pulmonary diseases, preeclampsia or eclampsia, hypertension, and diabetes, below high school education, gravidity more than 3, surgery more than 90-minute, failed or partial Sspinal anesthesia, fetal distress, Intrauterine Growth Restriction (IUGR), multiple pregnancies.

Intervention groups

Group one:40 patients received 15mg/kg iv. acetaminophen (diluted in 100 cc normal saline solution), Group two:40 patients received 0.5mg/kg iv meperidine Group three:40 patients received 15mg/kg iv. acetaminophen + 0.5mg/kg

Main outcome variables

pain score, nausea, vomiting, shivering, headache.

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20141009019470N75**

Registration date: **2018-05-04, 1397/02/14**

Registration timing: **retrospective**

Last update: **2018-05-04, 1397/02/14**

Update count: **0**

Registration date

2018-05-04, 1397/02/14

Registrant information

Name

Farzaneh Masihi

Name of organization / entity

Country

Iran (Islamic Republic of)

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+98 71 3647 4270

Email address

masihif@sums.ac.ir

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2018-01-05, 1396/10/15

Expected recruitment end date

2018-03-06, 1396/12/15

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison the Analgesic Effects of Acetaminophen, Meperidine, and their Combination on Postoperative Pain Management in Elective Cesarean Section Surgeries under Spinal Anesthesia

Public title

Comparison the Analgesic Effects of Acetaminophen, Meperidine, and their Combination in Elective Cesarean Section Surgeries under Spinal Anesthesia

Purpose

Prevention

Inclusion/Exclusion criteria

Inclusion criteria:

full-term pregnant women aged 18 to 40 years old
American Society of anesthesiologists physical status classification I(ASA I) undergoing elective cesarean section under spinal anesthesia

Exclusion criteria:

contraindications for meperidine or acetaminophen
history of alcoholism drug abuse convulsion migraine
dicopathy hepatitis renal failure cardiovascular or pulmonary diseases preeclampsia or eclampsia,
hypertension diabetes, gravidity more than 3 surgery more than 90-minute failed or partial S/A, Intrauterine Growth Restriction (IUGR), multiple pregnancies fetal distress

Age

From **18 years** old to **40 years** old

Gender

Female

Phase

2-3

Groups that have been masked

- Participant
- Investigator

Sample size

Target sample size: **120**

Randomization (investigator's opinion)

Randomized

Randomization description

Patients were randomized according to the charts which was derived from www.randomization.com site.

Blinding (investigator's opinion)

Double blinded

Blinding description

pregnant woman undergoing cesarean section and investigators were blinded to the study treatments.

Placebo

Not used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics committee of Shiraz University of Medical Sciences

Street address

Vice Chancellor of research, Shiraz University of Medical Sciences, 7th floor, central building of Shiraz University of Medical Sciences, Zand street

City

Shiraz

Province

Fars

Postal code

7134844119

Approval date

2017-12-22, 1396/10/01

Ethics committee reference number

IR.SUMS.MED.REC.1396.110

Health conditions studied

1

Description of health condition studied

Elective Cesarean Section

ICD-10 code

O82

ICD-10 code description

Encounter for cesarean delivery without indication

Primary outcomes

1

Description

Pain score

Timepoint

At 1, 2, 4, 6, 12, and 24 h after the surgery

Method of measurement

Visual Analogue Scale (VAS)

2

Description

Nausea and vomiting,

Timepoint

At 1, 2, 4, 6, 12, and 24 h after the surgery

Method of measurement

Observation

3

Description

Shivering

Timepoint

At 1, 2, 4, 6, 12, and 24 h after the surgery

Method of measurement

Observation

4

Description

Headache

Timepoint

At 1, 2, 4, 6, 12, and 24 h after the surgery

Method of measurement

Observation

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 40 patients received 15mg/kg iv. acetaminophen (diluted in 100 cc normal saline solution)

Category

Treatment - Drugs

2

Description

Intervention group: 40 patients received 0.5mg/kg iv meperidine

Category

Treatment - Drugs

3

Description

40 patients received 15mg/kg iv. acetaminophen + 0.5mg/kg meperidine within 15 minutes.

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Hafez hospital

Full name of responsible person

Zeinab Sadat Fattahi Saravi

Street address

Chamran boulevard , Hafez hospital

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Dr Seed Basir Hashemi

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Vice chancellor of research,7th floor of central building of Shiraz University of Medical Sciences, Zand street

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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

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

Person responsible for general inquiries

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Laleh Dehghanpishe

Position

Anesthesiologist

Latest degree

Specialist

Other areas of specialty/work

Anesthesiology

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Person responsible for scientific inquiries

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Position

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Specialist

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Person responsible for updating data

Contact

Name of organization / entity

Shiraz University of Medical Sciences

Full name of responsible person

Farzaneh Masihi

Position

MS in English Teaching, BS in anesthesia/English Consultant

Latest degree

Master

Other areas of specialty/work

Others

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Sharing plan

Deidentified Individual Participant Data Set (IPD)

Undecided - It is not yet known if there will be a plan to make this available

Study Protocol

Undecided - It is not yet known if there will be a plan to make this available

Statistical Analysis Plan

Undecided - It is not yet known if there will be a plan to make this available

Informed Consent Form

Undecided - It is not yet known if there will be a plan to make this available

Clinical Study Report

Undecided - It is not yet known if there will be a plan to make this available

Analytic Code

Undecided - It is not yet known if there will be a plan to make this available

Data Dictionary

Undecided - It is not yet known if there will be a plan to make this available