Clinical Trial Protocol
Iranian Registry of Clinical Trials

17 Sep 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
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Iran (Islamic Republic of)
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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
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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
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Anesthesiologist
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Person responsible for updating data

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Latest degree

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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