Clinical Trial Protocol
Iranian Registry of Clinical Trials

03 Jul 2026

Comparison of the analgesic effect of intravenous paracetamol combind meperidine and mepridine alone after elective caesarean

Protocol summary

Summary

In this study, 70 pregnant women, ASA I, II, candidate for Repeat II elective Caesarean Section, are randomized into two equal groups. Cesarian section is performed by spinal anesthesia with 60mg Lidocaine 5% .The control group receives 25 mg meperidine plus 6 ml intravenous normal saline15 minutes before the end of surgery.The intervention group receives 25 mg meperidine and 6 ml (1 gram) intravenous Paracetamol 15 minutes before the end of surgery. Then control group receives 6 ml intravenous normal saline and intervention group 6 ml (1 gram) intravenous Paracetamol every 6 hours in 6,12,18 hours. At any time if the patient's pain score greater than 4 based on visual criteria, meperidine 25 mg IV is injected. Time of first dose and the total amount of meperidine administered within 24 hours is recorded. Side effects including nausea, vomiting, itching, respiratory depression , dizziness and headaches are recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201203117752N4**
Registration date: **2012-05-23, 1391/03/03**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2012-05-23, 1391/03/03

Registrant information

Name

Parviz Amri Maleh

Name of organization / entity

Babol University of Medical Sciences

Country

Iran (Islamic Republic of)

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Recruitment status

Recruitment complete

Funding source

Vice-chancellor for research- Babol University of Medical science

Expected recruitment start date

2011-09-23, 1390/07/01

Expected recruitment end date

2012-09-22, 1391/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of the analgesic effect of intravenous paracetamol combind meperidine and mepridine alone after elective caesarean

Public title

Comparison of the analgesic effect of intravenous paracetamol combind meperidine and mepridine alone after elective caesarean

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria:Pregnant women , 18-40 years, class I,II America Society of Anesthesiology; Elective repeat II cesarean section with spinal anesthesia . Exclusion criteria: patients who are taking narcotic and analgesic, contraindication for intravenous meperedineor paracetamol ,history of alcoholism or uncontrolled

consumption of a drug. emergency cesarean surgery,duration of surgery more than an hour,Prescribed narcotic or other drugs because of inadequate levels of the spinal anesthesia

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

Gender
Female

Phase
N/A

Groups that have been masked
No information

Sample size
Target sample size: **70**

Randomization (investigator's opinion)
Randomized

Randomization description

Blinding (investigator's opinion)
Single blinded

Blinding description

Placebo
Used

Assignment
Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Vice-chancellor of research of Babol University of Medical Sciences

Street address
Gangafrooz St, Babol University of Medical Sciences

City
Babol

Postal code
4717641367

Approval date
2012-02-28, 1390/12/09

Ethics committee reference number
30/5895/39/ژ/پ

Health conditions studied

1

Description of health condition studied
Elective cesarean section

ICD-10 code
O82.0

ICD-10 code description
Delivery by elective caesarean section

Primary outcomes

1

Description
pain

Timepoint
24 hours

Method of measurement
Visual Analog Scale

Secondary outcomes

empty

Intervention groups

1

Description
In intervention group 1 gr. IV Acetaminophen administrate 15 min. before end of surgery and Q6hours to 24 hours.

Category
Treatment - Drugs

2

Description
In control group, Iv meperidine 25 mg administrate 15 min. before end of surgery and Q6hours to 24 hours.

Category
Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center
Rohani teaching Hospital

Full name of responsible person
Amri, Parviz

Street address
Gangafrooz St, Rohani teaching Hospital

City
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Sponsors / Funding sources

1

Sponsor

Name of organization / entity
Vice-chancellor for research of Babol University of Medical Sciences

Full name of responsible person
Mostafazadeh, Amrolah

Street address
Babol,Gangafrooz St, ,Babol University of Medical Science

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Babol

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 of Babol 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

Babol University of Medical Sciences

Full name of responsible person

Amrimaleh, Parviz

Position

Anestesiologist, FCCM

Other areas of specialty/work

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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