

Clinical Trial Protocol

Iranian Registry of Clinical Trials

28 Jul 2026

Clinical trial of comparison between the effect of paracetamol (Apotel) and meperidine (pethidine) on the pain in the first 24 hours after cesarean section.

Protocol summary

Summary

Objectives: Comparison between analgesic effect of paracetamol (Apotel) and meperidine (pethidine) in the first 24 hours after cesarean section. Design: Randomized clinical trial. Setting and conduct: Double blind. Participants: Inclusion criteria: all patients after cesarean section with normal body mass index(between 18.5 and 25). Exclusion criteria: Drug abuse; history of allergy to paracetamol or meperidine; history of hepatitis; renal failure ; heart failure, respiratory disease; CNS disorders; coagulopathy; sedative use; psychiatric disorders and complication of cesarean section. Interventions: Administration of paracetamol (Apotel) and meperidine (Pethidine). Main outcome: Pain relief in the first 24 hours after surgery.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201405262624N17**
Registration date: **2015-04-25, 1394/02/05**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2015-04-25, 1394/02/05

Registrant information

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Name of organization / entity

Iran University of Medical Sciences

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Recruitment status

Recruitment complete

Funding source

Investigator.

Expected recruitment start date

2014-08-23, 1393/06/01

Expected recruitment end date

2015-02-20, 1393/12/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of comparison between the effect of paracetamol (Apotel) and meperidine (pethidine) on the pain in the first 24 hours after cesarean section.

Public title

Analgesic effect of paracetamol and meperidine after cesarean section.

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: all patients after cesarean section with normal body mass index(between 18.5 and 25).

Exclusion criteria: Drug abuse; history of allergy to paracetamol or meperidine; history of hepatitis; renal failure; heart failure; respiratory disease; CNS disorders; coagulopathy; sedative use; psychiatric disorders and complication of cesarean section.

Age

No age limit

Gender

Female

Phase

3

Groups that have been masked*No information***Sample size**Target sample size: **100****Randomization (investigator's opinion)**

Randomized

Randomization description**Blinding (investigator's opinion)**

Double blinded

Blinding description**Placebo**

Not used

Assignment

Parallel

Other design features**Secondary Ids**

empty

Ethics committees**1****Ethics committee****Name of ethics committee**

Ethic committee of Iran University of Medical Sciences

Street address

Hemmat highway, Chamran Cross

City

Tehran

Postal code

16117

Approval date

2012-09-23, 1391/07/02

Ethics committee reference number

92/2592 /130/3

Health conditions studied**1****Description of health condition studied**

Cesarean delivery

ICD-10 code

O82

ICD-10 code description

Single delivery by caesarean section

Primary outcomes**1****Description**

Pain .

Timepoint

0-1-2-4 and 6 hours after drug administration.

Method of measurement

VAS

Secondary outcomes**1****Description**

need to more analgesic

Timepoint

0-1-2-4 and 6 hours after drug administration.

Method of measurement

questionair

2**Description**

Paracetamol adverse effects.

Timepoint

0-1-2-4 and 6 hours after drug administration.

Method of measurement

VAS

3**Description**

side effects of meperidine

Timepoint

0-1-2-4 and 6 hours after drug administration.

Method of measurement

VAS

Intervention groups**1****Description**

Intervention group: After finishing cesarean section and in the recovery room , pain of the patient has been determined using VAS . Then diclofenac suppository 100 milligram plus paracetamol (Apotel) ampule has been prescribed 1 mg every 8 hours (infusion in 100 ml normal saline during 15 minutes).

Category

Treatment - Drugs

2**Description**

Control (mepiridine) group: After finishing cesarean section and in the recovery room , pain of the patient has been determined using VAS . Then diclofenac suppository 100 milligram plus mepiridine (pethidine) 50 mg has been prescribed every 6 hours intramuscularly.

Category

Treatment - Drugs

Recruitment centers**1****Recruitment center**

Name of recruitment center
Akbarabadi Teaching Hospital
Full name of responsible person
Maryam Kashanian
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Person responsible for scientific inquiries

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Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Vice chancellor for research ,Iran University of Medical Sciences.
Full name of responsible person
Dr Seyed Ali Javad Mousavi
Street address
Hemmat High way, Chamran Cross.
City
Tehran
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 ,Iran 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

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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