

Clinical Trial Protocol

Iranian Registry of Clinical Trials

09 Jun 2026

Comparison of intravenous injection of acetaminophen (apotel) and pethidine on the severity of postoperative pain in patients with cesarean section under spinal anesthesia

Protocol summary

Summary

Objectives: Comparison of intravenous injection of acetaminophen (apotel) and pethidine on the severity of postoperative pain in patients with cesarean section under spinal anesthesia in Sayyad Shirazi Hospital. Study design: Population of study: 80 women aged 17 to 40 years old. Groups of study: The first group received intravenous acetaminophen (1000 mg), group 2: pethidine (1mg / kg), simple randomized, double blind. Inclusion criteria: Elective surgery- no allergic reaction. exclusion criteria: Dissatisfied to participate in the study -having liver or renal disease. B- Interventions: Determine Severity of pain at hours 0, 2, 4, 6, hours after anesthesia and administration of drugs in two groups. The severity of pain with using criteria standard (VAS). C- time of intervention: In recovery after surgery. D- Main outcomes: Determine the severity of pain in the two drug groups.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT201407099697N4**
Registration date: **2017-09-04, 1396/06/13**
Registration timing: **retrospective**

Last update:

Update count: **0**

Registration date

2017-09-04, 1396/06/13

Registrant information

Name

Fozieh Bakhsha

Name of organization / entity

Golestan University of Medical Science

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Recruitment status

Recruitment complete

Funding source

Vice Chancellor for Research and Technology

Expected recruitment start date

2016-01-21, 1394/11/01

Expected recruitment end date

2016-09-22, 1395/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Comparison of intravenous injection of acetaminophen (apotel) and pethidine on the severity of postoperative pain in patients with cesarean section under spinal anesthesia

Public title

Comparison of intravenous injection of acetaminophen (apotel) and pethidine on the severity of postoperative pain in patients with cesarean section under spinal anesthesia

Purpose

Treatment

Inclusion/Exclusion criteria

Inclusion criteria: Patients with 1 and 2 ASA class of Anesthesia; Term gestational age; absence of chronic diseases such as cardiovascular; hepatic and renal

disease. exclusion criteria: hypersensitivity to any drug such as acetaminophen; local anesthetics and opioid; having liver or renal disease; diabetes, and patients who used analgesic drugs (opioids, NSAID and corticosteroid) within 8 to 12 hours before the intervention.

Age

From **17 years** old to **40 years** old

Gender

Female

Phase

N/A

Groups that have been masked

No information

Sample size

Target sample size: **80**

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

Ethics Committee of Golestan University of Medical Sciences

Street address

Vice Chancellor for Research and Technology, Golestan University of Medical Sciences, at the beginning of Shat Kola road, Hirkan blvd, Gorgan

City

Gorgan

Postal code

49341-74515

Approval date

2015-02-08, 1393/11/19

Ethics committee reference number

9309052108412

Health conditions studied

1

Description of health condition studied

Acute pain

ICD-10 code

R52.0

ICD-10 code description

Acute Pain

Primary outcomes

1

Description

Severity of pain

Timepoint

at Hour 0, 2, 4, 6

Method of measurement

Visual Scale of Pain

Secondary outcomes

empty

Intervention groups

1

Description

intravenous acetaminophen 1000mg, based on average pain severity at Hour 0, 2, 4, 6 after local anesthetic in the recovery unit, Daroupakhsh Pharmaceutical product

Category

Treatment - Drugs

2

Description

Pethidine 1 mg per kg body weight, based on average pain severity at Hour 0, 2, 4, 6 after local anesthetic in the recovery unit, Daroupakhsh Pharmaceutical product

Category

Treatment - Drugs

Recruitment centers

1

Recruitment center

Name of recruitment center

Sayyad Shirazi Hospital of Gorgan

Full name of responsible person

Street address

City

Gorgan

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Vice Chancellor for Research and Technology of Golestan University

Full name of responsible person

Mohammad Hossein Tazikeh, Director of Vice Chancellor Research and Technology

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Vice Chancellor for Research and Technology, Golestan University of Medical Sciences, at the beginning of Shat Kola road, Hirkan blvd, Gorgan, Golestan

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Gorgan

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 and Technology of Golestan University

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**

Golestan University of Medical Sciences

Full name of responsible person

Fozieh Bakhsha

Position

MSc of Nurse anesthesiology, Instructor of school of paramedical sciences

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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