Clinical Trial Protocol
Iranian Registry of Clinical Trials

10 Jun 2026

Clinical trial of analgesic effect of intraperitoneal Bupivacaine-Petidine infiltration compared with intravenous after diagnostic gynecologic laparpscopy

Protocol summary

Summary

Recently most of laparoscopic surgeries especially gynecologic procedures are performed in an outpatient basis. Post operative pain is usually treated by opioids, which is expensive and may induce various side effects. Women experience moderate-to-severe pain on the first day after diagnostic laparoscopy. The aim of this study was to assess the efficacy of multimodal early premedication to prevent pain after laparoscopy. Following approval from the Local Ethics Committee and receipt of written informed consent, 90 ASA physical status I-II patients who underwent diagnostic laparoscopy will be randomly divided into two groups. General anesthesia will be standardized. The patients in group 1 will receive Paracetamol 1 g IV and intraperitoneal normal saline, 10 minutes before the end of operation. Group 2 will receive normal saline IV and intraperitoneal bupivacaine 0.25%, 40 ml with pethidine 50 mg, 10 minutes before the end of operation. The drugs will be prepared in covered syringes and will be injected blindly with an anesthesiologist who has performed anesthesia or with gynecologist(intraperitoneal drugs). Pain will be assessed and recorded by Visual Analogue Scale after arrival to the postanesthesia care unit and at 2, 4, 6, 8, 12 and 24 th hours postoperatively. Pethidine 0.5-1 mg/kg IV will be administered to the patient with VAS higher than 5. First analgesic request, total analgesia doses, and any other postoperative complications including nausea-vomiting and sedation also will be recorded.

General information

Acronym

IRCT registration information

IRCT registration number: **IRCT2013072810765N4**
Registration date: **2014-02-22, 1392/12/03**
Registration timing: **registered_while_recruiting**

Last update:
Update count: **0**

Registration date

2014-02-22, 1392/12/03

Registrant information

Name

Sousan Rasooli

Name of organization / entity

Alzahra hospital/Tabriz University of Medical Sciences

Country

Iran (Islamic Republic of)

Phone

+98 41 1553 9161

Email address

rasoolis@tbzmed.ac.ir

Recruitment status

Recruitment complete

Funding source

Tabriz University of Medical Sciences

Expected recruitment start date

2014-02-20, 1392/12/01

Expected recruitment end date

2014-09-23, 1393/07/01

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

Clinical trial of analgesic effect of intraperitoneal Bupivacaine-Petidine infiltration compared with intravenous after diagnostic gynecologic laparpscopy

Public title
Clinical trial of analgesic Effect of intraperitoneal bupivacaine-petidine infiltration compared with intravenous paracetamol on Post gynecologic diagnostic laparoscopic pain
Purpose
Prevention
Inclusion/Exclusion criteria
Inclusion criteria:Women with 20-38 years old; candidated for gynecologic diagnostic Laparoscopy; patients with ASA physical status I and II; patients who will give written informed consent Exclusion criteria: Women with ASA physical status III or higher;patients who received analgesic; patients who had contraindication for NSAIDs or Paracetamol like peptic ulcer; coagulopathy; renal failure;hepatic failure; allergy
Age
From **20 years** old to **38 years** old
Gender
Female

Phase
2-3
Groups that have been masked
No information
Sample size
Target sample size: **90**
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 for Reaserch, Tabriz University of Medical Sciences
Street address
Tabriz University of medical Sciences, Golgasht Ave, Tabriz
City
Tabriz
Postal code
Approval date
2013-11-27, 1392/09/06
Ethics committee reference number
92138

Health conditions studied

1

Description of health condition studied
Change in pain after laparoscopy
ICD-10 code
ICD-10 code description

Primary outcomes

1

Description
Postoperative pain
Timepoint
2, 4, 6, 8, 12, 24 hours postoperative
Method of measurement
with the use of visual Analogue Scale

Secondary outcomes

1

Description
Sedation
Timepoint
2, 4, 6, 8, 12, 24 hours post operative
Method of measurement
with the use of modified Ramssy sedation scoring

Intervention groups

1

Description
The patients in group 1 will receive Paracetamol 1 g IV and normal saline intraperitoneal, 10 minutes before the end of operation
Category
Treatment - Drugs

2

Description
Group 2 will receive normal saline IV and intraperitoneal bupivacaine 0.25%, 40ml –pethidine 50 mg, 10 minutes before the end of operation.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Alzahra Hospital
Full name of responsible person
Dr.Sousan Rasouli
Street address

South Artesh Ave, Alzahra Hospital, Tabriz, Iran

City

Tabriz

Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr. Sousan Rasouli

Street address

South Artesh Ave, Alzahra Hospital, Tabriz, Iran

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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

Tabriz 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

Alzahra Hospital

Full name of responsible person

Dr.Sousan Rasooli

Position

Associated Professor, Specialist in Anesthesiology

Other areas of specialty/work

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Other areas of specialty/work

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Person responsible for updating data

Contact

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