

Clinical Trial Protocol

Iranian Registry of Clinical Trials

22 Jul 2026

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

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

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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 laparoscopy

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; candidates 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 Research, 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 Ramsay 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

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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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Name of organization / entity

Tabriz University of Medical Sciences

Full name of responsible person

Dr.Sousan Rasooli

Position

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Other areas of specialty/work

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Web page address

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