

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

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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 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

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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

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South Artesh Ave, Alzahra Hospital, Tabriz, Iran

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Tabriz

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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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